

USE OF PEPPERMINT OIL TO PROMOTE URINATION IN WOMEN

EXPERIENCING POSTOPERATIVE URINARY RETENTION

by

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ABSTRACT

Urinary retention is a common postsurgical complication that places patients at risk for increased morbidity, prolonged recovery, and adverse surgical outcomes. Practicing nurses provide anecdotal support for peppermint oil use, however significant aspects for the administration, safety, and efficacy are uncertain or unknown. This comparative descriptive study investigated the use of peppermint oil as a nursing measure to stimulate voiding in women experiencing urinary retention during the first 12 hours after surgery. Guided by the Roy Adaptation Model, the Postoperative Urinary Retention Assessment (PURA) instrument was developed for data collection with a convenience sample of women ($N = 73$) in two hospital settings. Data from postoperative subjects ($n = 48$) were analyzed to describe contextual (age, fluid intake, medication use) and residual (type of surgery, type of anesthesia) stimuli, and responsiveness to intervention with peppermint oil. The Peppermint Oil Administration Protocol (POAP) served as the standard for the preparation and administration of peppermint oil. Four subjects (8%) developed postoperative urinary retention. Three subjects voided after intervention with peppermint oil, one did not. There were no adverse reactions to peppermint oil administration detected at either one of the two follow up assessments performed by the investigator, suggesting that peppermint oil was well tolerated by study subjects. No clear pattern emerged from the comparisons of contextual (age, fluid intake,

medication use) and residual (type of surgery, type of anesthesia) stimuli examined by the questions for research. Findings from this study provide limited support for the use of peppermint oil as a nursing intervention for acute urinary retention and point to the need for further examination of this clinical practice.

DEDICATION

This thesis is dedicated in loving memory to my father, Milo G. York.

Papa, this one is for you.

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Chapter 1

Introduction

Familiarity with noninvasive nursing measures to promote voiding in patients with acute urinary retention, such as providing privacy or running water in a sink, are generally considered to be fundamental nursing knowledge. Routine clinical implementation of these measures would rarely be considered unusual, unwarranted, or inappropriate nursing action. One nursing measure that is less well known, yet still is mentioned in a number of nursing texts involves the use of peppermint oil, an aromatic plant oil, to stimulate voiding (Lederer, Marculescu, Mocnik, & Seaby, 1991; Sherwen, Scoloveno, & Weingarten, 1995; Tucker, Canobbio, Paquette, & Wells, 1996; Vogler, 1993).

Numerous nurses were informally surveyed by this investigator to elicit anecdotal experiences related to the use of an aromatic oil for this purpose. Although a number of the nurses surveyed reported having had actual experience using an aromatic oil for patients with postoperative urinary retention, many others reported no prior knowledge of this practice. The nurses who were experienced in aromatic oil usage consistently endorsed the oils as safe, effective, and well received by patients, however none were familiar with the origin of the practice. Furthermore, these nurses overwhelmingly reported that a decision to incorporate an aromatic oil into clinical

practice was based upon the verbal recommendation of a more experienced nurse colleague and not on documented scientific principles or research findings.

Recorded information related to the origin, incidence, and efficacy of aromatics in general and peppermint oil in particular to stimulate voiding is obscure. A search of the nursing, medical, pharmaceutical, and aromatherapy literature failed to uncover a single theoretical or research based article related to the use of an aromatic oil to promote voiding. No accurate, reliable body of knowledge exists to support the use of peppermint oil for patients with postoperative urinary retention. Thus, validation for this nursing clinical knowledge is needed to support the use of peppermint oil in contemporary nursing practice.

Statement of Purpose

Practicing nurses provide support for the use of peppermint oil in acute urinary retention, yet significant aspects of the use of peppermint oil including administration guidelines, benefits, risks, and clinical efficacy are uncertain. The purpose of this study was to investigate the use of peppermint oil as a nursing measure for adult women experiencing postoperative urinary retention.

Research Questions

A comparative descriptive study using the Roy Adaptation Model as a theoretical framework was designed to answer three research questions.

1. What is the difference between adult women who do and do not develop postoperative urinary retention with regard to selected contextual (age) and residual stimuli (type of surgery, type of anesthesia)?
2. What is the difference between women with postoperative urinary retention who do and who do not void after the administration of peppermint oil with regard to selected contextual stimuli (age, fluid intake, medication use)?
3. What is the difference between women with postoperative urinary retention who do and do not void after the administration of peppermint oil with regard to selected residual stimuli (type of surgery, type of anesthesia)?

Background

Controlled urine retention and elimination by voiding is a normal function of the neurologically intact lower urinary tract. The lower urinary tract is composed of the bladder and urethra; the bladder serves to store and void, and the urethra to control and convey (International Continence Society, 1990). In acute urinary retention, there is a sudden inability of the bladder to empty appropriately, despite adequate urine production. Acute urinary retention is an important issue for postoperative, spinal cord injured, and postpartum patients, however this study was limited to female postoperative patients.

Assuming the absence of preexisting urinary tract pathologies, the etiology for postoperative urinary retention may include bladder outflow obstruction, decreased

detrusor contractility, inhibition of the voiding reflex, or impaired bladder sensation (Anderson & Grant, 1991). Regardless of etiology, Stallard and Prescott (1988) contend the morbidity risk for a single episode of postoperative urinary retention is significant and potentially serious. Unrelieved urinary retention can lead to bladder distention, ischemia, urine stasis, vesicoureteral reflux, diminished detrusor tone, and bacteriuria (Black & Matassarini-Jacobs, 1997; Tammela, Kontturi, & Lukkarinen, 1986b).

Untreated acute urinary retention is a urologic emergency that places a postoperative patient at risk for prolonged recovery and negative surgical outcomes (Phipps, Cassmeyer, Sands, & Lehman, 1995). Postoperative urinary retention is reported to occur in 7% to 25% of postsurgical patients (Tammela et al., 1986b), however incidence rates have been documented to be as high as 50% following abdominal surgery (n = 20) (Petersen, Husted, Rybo, Schurizek, & Wernberg, 1982), 52% after anorectal surgeries (Prasad & Abcarian, 1978), 61% after general surgeries (n = 100) (Kemp & Tabaka, 1990), and 62% after hip arthroplasty (n = 32) (Walts, Kaufman, Moreland, & Weiskopf, 1985).

The initial treatment of postoperative urinary retention includes a number of noninvasive measures traditionally considered to be within the domain of nursing practice (Kozier, Erb, Blais, & Wilkison, 1995; Lewis, Collier, & Heitkemper, 1996; Phipps et al., 1995). Documented nursing measures to promote voiding in the

postoperative patient generally focus on adequate pain control, psychological support, positioning, and measures to relax the urinary sphincter. Nursing studies related to the use and efficacy of noninvasive measures were not found, however two medical studies did report findings specific to the implementation of noninvasive measures to stimulate voiding in general surgery patients with postoperative urinary retention.

Treiger, Tovarek, and Casciato (1950) report that the use of physiopsychologic measures, such as providing reassurance, having the patient drink water, using the sound of running water, and having the patient assume a sitting or standing position, reduced the incidence of catheterization for postoperative urinary retention from 18.3% to 1.7% ($n = 1000$). Stallard and Prescott (1988) report that 70% of patients who experienced difficulty voiding after surgery ($n = 30$) were able to void “with the help of simple measures, administered by nursing staff” (p. 1142). Examples of the simple nursing measures cited by these authors included providing the patient with privacy, giving a dose of oral analgesic, having the patient sit in a hot bath, and having the patient stand to void.

One noninvasive measure (Doenges & Moorhouse, 1996; Lederer et al., 1991; McCloskey & Bulechek, 1996; Sherman, 1992; Sherwen et al., 1995; Tucker et al., 1996; Vogler, 1993) to relax the urinary sphincter and initiate the voiding reflex involves the use of an aromatic substance such as wintergreen oil (*Gaultheria procumbens*) or peppermint oil (*Mentha piperita*). Although both wintergreen oil and

peppermint oil are recommended in the literature, there are significant differences in the chemical composition, mechanism of action, medicinal properties, and safety of these two aromatic oils.

Wintergreen oil is composed of methyl salicylate, an aspirin-like compound. Although synthetic methyl salicylate preparations are used widely in small amounts as flavoring agents and forest-type fragrances, Lawless (1992) contended the natural form of wintergreen oil is toxic, irritating, and sensitizing, and internal or external exposure should be avoided. Historically, wintergreen oil preparations have been used as counterirritants to relieve musculoskeletal pain and inflammation, and as antitussives (Hoover, 1975; Lawless, 1992). The Nursing Interventions Classification (NIC), a nationally recognized, comprehensive, standardized taxonomy of nursing interventions included use of spirits of wintergreen as a nursing action under the Urinary Retention Care intervention label (McCloskey & Bulechek, 1996).

Peppermint oil is a complex chemical compound. The primary constituent of peppermint oil is menthol, although at least 10 other compounds are known to exist in the natural form (Hills & Aaronson, 1991). Peppermint oil is commonly used by lay persons as a flavoring agent, carminative, antispasmodic, local anesthetic, and as an antiemetic in pregnancy (Burns & Blamey, 1994; Hoover, 1975; Lawless, 1992). Although no scientific investigations specific to the use of peppermint oil to promote urine elimination were discovered, investigators have reported that

peppermint oil acts as a calcium channel antagonist to produce relaxation of gastrointestinal smooth muscle (Taylor, Duthie, & Luscombe, 1985). It is possible that peppermint oil also acts as a calcium channel antagonist in urinary smooth muscle and may explain the oil's usefulness in relieving urinary retention.

The Joint Food Additives Organization/World Health Organization (FAO/WHO) Expert Committee on Food Additives has established an acceptable oral intake for peppermint oil at 0.2 mg/kg of body weight per day (Thorup, Wurtzen, Carstensen, & Olsen, 1983). A parameter for topical exposure to peppermint oil through direct or vapor contact was not found, however reports of adverse effects are not common even with long term, ubiquitous exposure to food, drink, tobacco, and medicinal products containing peppermint oil (McGowan, 1966; Morton, Garioch, Todd, Lamey, & Forsyth, 1995).

No information related to the origin, incidence, and efficacy of peppermint oil usage in acute urinary retention was found. A general procedure and rationale for peppermint oil use was provided by Tucker et al. (1996) and Vogler (1993). These authors reported that a few drops of peppermint oil placed into a bedpan or urinal, or on a cotton ball held in front of the urinary meatus produce vapors that rise to the perineum, relax the urinary sphincter and facilitate voiding. Lederer et al. (1991) recommend "having [the] patient inhale oil of peppermint" to encourage voiding (p. 197). Unfortunately, Lederer et al. did not specify the amount of oil to use, the

procedure for administration of the oil, or the mechanism of action for inhaled peppermint oil. Attempts to contact these authors for further clarification were unsuccessful.

Urinary catheterization is recommended to provide prompt bladder decompression and alleviation of patient discomfort when noninvasive measures are unsuccessful or the physician ordered time limit for the first postoperative voiding has been exceeded (Fuselier, 1993; Pollack & Nyhus, 1983; Williams, Wallhagen, & Dowling, 1993). The time range before urinary catheterization was deemed necessary varied by source, but most often ranged between 6 and 12 hours (Hinman, 1976; Holloway, 1993; Walts et al., 1985).

Treatment by indwelling or straight urinary catheterization, albeit effective, carries significant risk for morbidity and negative outcomes (Belfield, 1988; Hart, 1985; Hooton, 1990; Stamm, 1991). Urinary catheterization is an invasive procedure that has been reported to cause urethral trauma, patient discomfort, and urinary tract infection (UTI) (Taube & Gajraj, 1989). The literature is replete with admonitions to limit urinary catheterizations to only those cases where the benefits clearly outweigh the risks or when it is the only means to obtain diagnostic information and therapeutic results (Carson, 1988; Hart, 1985; Schaeffer, 1986).

Catheter-associated bacteriuria represents the most common cause of postoperative UTI (Black & Matassarini-Jacobs, 1997) and may interfere with

postoperative rehabilitation (Smith & Marrant, 1990). The risk of catheter-associated UTI increases linearly with each day of indwelling catheterization (Haley, Hooton & Culver, 1981), and invariably occurs within one week (Carson, 1988). The development of a catheter-associated UTI has been linked to a threefold greater risk of mortality in hospitalized patients (Cox, 1988). Research findings indicate that female patients have higher rates of catheter-associated UTIs than male patients (Carson, 1988; Hart, 1985; Schaeffer, 1986; Stamm, 1991). In addition, catheter-associated UTIs are linked to an increased incidence of wound infections, longer length of postoperative stay (Carson, 1988), and increased cost of hospitalization (Carson, 1988; Haley, Culver, White, Morgan, & Emori, 1985; Hart, 1985).

Primary prevention of acute urinary retention would provide a logical approach to reduce the incidence of postoperative urinary retention, yet pharmacological prophylaxis with parasympathomimetic agents, specifically bethanechol chloride, has not been proven to be statistically effective (Bowers et al., 1987; Finkbeiner, 1985). Routine preemptive catheterization could be employed, but would unnecessarily expose all surgical patients to the inherent risks and negative outcomes associated with the procedure. Attempts to prevent the development of postoperative urinary retention are further complicated by an inability to accurately predict which patients will develop this postsurgical complication (Michelson, Lotke, & Steinberg, 1988), and in fact, acute postoperative urinary retention may represent a

patient's first clinical episode of urinary dysfunction (Anderson & Grant, 1991).

Studies designed to identify patients who are at an increased risk for the development of postoperative urinary retention on the basis of age, gender, prior history of urinary symptoms, type of anesthesia, perioperative fluid intake, and administration of narcotic analgesics have produced equivocal results (Wynd, Wallace, & Smith, 1996).

As primary prevention of postoperative urinary retention is not always possible, secondary prevention through early detection and prompt intervention represents an important nursing strategy for mitigating the negative outcomes associated with acute urinary retention and urinary catheterization. Routine, appropriate nursing assessments of fluid balance and urinary elimination would enhance early detection of postoperative urinary retention. Timely intervention with noninvasive nursing measures such as the use of peppermint oil would promote patient voiding and forestall the need for urinary catheterization.

Theoretical Framework

Selected concepts from the Roy Adaptation Model were used to guide study design and identify study variables. In the Roy model, Person is conceptualized as a biopsychosocial adaptive system in constant interaction with a changing internal and external environment (Roy & Andrews, 1991). Input from the environment in the form of stimuli and adaptation level activate internal regulator and cognator coping

mechanisms, which in turn produce behavioral responses in four adaptive modes: physiological, self concept, role function, and interdependence (Roy, 1984).

Roy (1984) categorized environmental stimuli as focal, contextual, and residual. The focal stimulus represents the stimulus most immediately confronting the individual, the object or event attracting one's attention, and the primary influence on behavioral responses (Roy & Andrews, 1991). Contextual stimuli contribute to the effect of the focal stimulus but are not the center of the person's energy or attention. Residual stimuli are environmental factors whose effects in the current situation are unclear or unknown. The pooled effect of the three types of stimuli form the adaptation level, or the ability of the individual to cope with the changing environment. Behavioral responses that promote integrity and contribute to the adaptation goals of survival, growth, reproduction and mastery are termed adaptive and responses that do not are termed ineffective (Roy & Andrews, 1991).

In the physiological mode, integrity is manifested in five basic needs and four complex physiologic processes (Roy & Andrews, 1991). The five basic needs are oxygenation, nutrition, elimination, activity, and rest. The four complex physiologic processes include the senses, fluids and electrolytes, neurological, and endocrine functioning. The self-concept mode focuses on the psychological and spiritual aspects of the person and is subdivided into the physical self and the personal self. The role function mode focuses primary, secondary, and tertiary roles occupied by the

individual in society. The interdependence mode focuses on interactions related to giving and receiving of love, respect, and value in nurturing relationships with others (Roy & Andrews, 1991).

Physiologic functioning with respect to postoperative urine elimination was the focus of this study. Patient behavior consistent with adaptation and physiologic integrity in the first 12 hours of the postoperative period was manifested by spontaneous voiding of bladder contents. The inability to void bladder contents with concomitant signs and symptoms of acute urinary retention during the same time period indicated an ineffective physiologic response.

Roy postulated that urinary retention could serve as a focal stimulus for the physiologic mode and that the influence of age, fluid intake, and medications were common contextual stimuli (Roy & Andrews, 1991). In addition, nursing interventions to promote adaptation would center on managing stimuli, in particular the focal stimulus, whenever possible. By altering, increasing, decreasing, or maintaining environmental stimuli, Roy posited that nursing could enhance an individual's ability to adapt or respond positively to changes in their environment (Roy & Andrews, 1991).

In this study, unrelieved postoperative bladder distention occurring during the first 12 hours after surgery represented the focal stimulus. The nursing intervention employed to manage the stimulus, and thereby promote adaptation, was the

administration of peppermint oil. In keeping with Roy's conceptualization of contextual stimuli and contributing factors for postoperative urinary retention identified in the literature review, the study included age, fluid intake, and medication use. Residual stimuli identified as having an unknown or unclear influence on a subject's ability to void were the type of surgical procedure performed and the type of anesthesia employed during the intraoperative period.

The Roy Adaptation Model has been used as a frame of reference for the development of nursing knowledge needed to guide practice in numerous nursing studies (Fawcett, 1989; Meleis, 1991; Roy & Andrews, 1991). Roy maintained that the Roy Adaptation Model has an important role in guiding basic and clinical nursing research and that research design based on selected model concepts is valid (Roy & Andrews, 1991). Roy does not specify any particular research design, instruments, or statistical methods that should, or should not be used in research utilizing the Roy adaptation model (Fawcett & Tulman, 1990).

Significance

In the absence of a national reporting system to accurately identify the incidence of postoperative urinary retention, it is difficult to predict the number of patients that could potentially benefit from the timely administration of a safe, effective nursing measure to promote voiding prior to catheterization. Nonetheless, surgical intervention is a significant component of patient health care in the United

States and all patients undergoing surgical intervention are at some degree of risk for postsurgical complications. Nursing has an important role in the early detection and effective management of postoperative complications. Postoperative urinary retention is a well recognized and relatively common postsurgical complication (Kemp & Tabaka, 1990; Tammela et al., 1986a) and as such, is of significant concern to nursing.

Bulechek and McCloskey (1992) contend that a clearly defined base of knowledge, one that defines “what it is that nurses do and whether what they do makes a difference” is the key to an autonomous profession (p. 1). Inherent in this perspective is the need for an accurate, reliable body of knowledge to support clinical decision making and from which predictable patient outcomes can be achieved (Hinshaw, 1988). Nursing intervention for postoperative urinary retention has heretofore focused on a cadre of noninvasive nursing measures that are perpetrated by common sense and tradition, or physician ordered urinary catheterization, but lack research support.

The implementation of unsubstantiated nursing measures is no longer an acceptable basis for the delivery of professional nursing care (Bulechek & McCloskey, 1992) and is in direct conflict with current professional nursing standards and the delivery of high quality, cost effective health care. In the American Nurses Association’s Standards of Clinical Practice (American Nurses Association [ANA],

1991) and the Association of Operating Room Nurses' Standards of Perioperative Professional Performance (Groah, 1996), nurses are charged with the responsibility for systematically evaluating the quality and effectiveness of nursing practice and use of interventions substantiated by research.

Nursing research that is clinically relevant, scientifically rigorous, and sensitive to measures for quality of care and cost factors of interest would facilitate professional decision making and investigation of nursing sensitive patient outcomes (Hinshaw, 1992). Given the purported but uncertain nature of peppermint oil as a nursing measure, the suggested use of peppermint oil raises critical questions. Does the use of peppermint oil merit a place in current nursing practice? Is it efficacious, safe, and cost effective? If so, in what context would it be best be utilized? In order to address these critical questions, investigation of the use of peppermint oil in clinical practice is warranted.

Assumptions

The research study is based on selected components of the Roy Adaptation Model and the following assumptions:

1. Peppermint oil is a complex substance and the mechanism of action is not fully known or understood.
2. The administration of peppermint oil does not pose a significant risk to the health and well being of an female adult postoperative patient.

3. Subjects are reliable to provide honest self-reports of subjective symptoms associated with postoperative urinary retention.

4. Registered nurses and licensed practical nurses possess the necessary knowledge and skill for accurate assessment of postoperative urinary retention.

Definition of Terms

acute urinary retention: a sudden inability of the bladder to empty appropriately, despite adequate urine production.

peppermint oil: “Volatile oil obtained from the overground parts of the flowering plant *Mentha piperita*” (Hills & Aaronson, 1991 p. 55). The peppermint oil used in this study will conform to standard established by the United States Pharmacopeia.

postoperative urinary retention: acute urinary retention occurring within the first 12 hours after a surgical procedure, with no evidence of pre-renal or acute renal failure.

Chapter 2

Review of the Literature

The literature review provides a basis for an understanding of major study concepts and variables. The review is organized into four sections. In the first section, an overview of normal voiding is presented. Discussion of the literature relevant to postoperative urinary retention in the second section is followed by research findings pertinent to the contributing factors for postoperative urinary retention identified as contextual and residual stimuli in this study. In the fourth section, clinical literature and research results pertaining to the use of peppermint oil is presented.

Normal Voiding

Voiding in the adult is normally a voluntary act with the urinary bladder, urethra, and pelvic floor muscles working together as a functional system to provide for the storage and elimination of urine (Gray, 1992). A delicate balance between the autonomic and somatic neurological control system and structural integrity of the urinary tract are essential to the process of normal voiding. The complex interaction of voluntary control and neural reflex networks in the brain, spinal cord, and peripheral ganglia maintain the balance between excitation and relaxation of bladder wall musculature (detrusor) and the internal and external urinary sphincters (Bhatia, 1984; de Groat, 1995). These neural networks are composed of numerous, interrelated sympathetic, parasympathetic, and somatic nerves.

During bladder filling, urine leakage from the bladder is prevented by a watertight seal created by contraction of the urethral sphincteric mechanism. As bladder volume approaches 150 to 300 ml, stretch receptors in the bladder wall are stimulated, which in turn trigger the spinal micturition reflex and the cerebral centers for reflex coordination and volitional control (Bullock, 1996). The micturition reflex simultaneously initiates detrusor contraction and relaxation of the internal urethral sphincteric mechanism to initiate voiding, provided inhibition through voluntary control mechanisms of the external urinary sphincter does not occur. If external sphincter inhibition does occur, bladder filling continues but voiding is delayed until a later time. If external sphincter inhibition does not occur, active detrusor contractions continue until the bladder is emptied by voiding. When the bladder is emptied, the urethral sphincteric mechanism once again contracts to reestablish the watertight seal and the process of bladder filling begins anew (de Groat, 1995).

A variety of neurologically active substances may ultimately evoke smooth muscle contraction in the lower urinary tract, however calcium is essential for the initiation of smooth muscle contraction (Ostergard, 1984). Ostergard (1984) postulated that extracellular calcium acts as a trigger for the release of intracellular calcium stores and the subsequent contraction of intracellular contractile proteins in urinary smooth muscle. This extracellular calcium most likely enters the cell via action-dependent channels or receptor-operated channels. These channels are opened

by interaction of a stimulant substance with receptor sites located in the cell wall; the greater the number of channels opened, the more pronounced the calcium influx, and consequently, the more intense the muscle contraction (Ostergard, 1984). A similar process for extracellular calcium stimulation of striated muscle contraction is described by Bullock (1996).

Although the structure and function of the lower urinary tract is similar in the male and female adult, gender specific differences are known to exist. In the female, the urethral sphincter mechanism is not an anatomic entity per se, but rather a combination of dynamic tension, compressive, and supportive physiologic forces produced by the various structural components of the lower urinary tract and pelvic musculature (Gray, Rayome, & Moore, 1995). The urethral smooth muscle located in the bladder base and proximal urethra of a female is less prominent and is primarily innervated by cholinergic receptors (Gray et al., 1995), whereas alpha-adrenergic receptors predominant in the male (Applebaum, 1980). During voiding, excitation of cholinergic receptors and inhibition of sympathetic receptor stimulation in the female reconfigures the urethra, producing a wider, shorter urethral conduit for urine flow. At the end of voiding, any urine remaining in the female urethra is emptied by gravity while in the male, the urethra is drained by voluntary bulbocavernosus muscle contractions (Black & Matassarini-Jacobs, 1997).

Postoperative Urinary Retention

Postoperative urinary retention occurs when an individual is unable to void bladder contents during the postoperative period (Kemp & Tabaka, 1990; Tammela, et al., 1986a), despite continued urine production (Black & Matassarini-Jacobs, 1997; Williams et al., 1993). With continued urine production, the bladder becomes over distended and the individual may experience dribbling and overflow incontinence (Doenges & Moorhouse, 1996). The North American Nursing Diagnosis Association (NANDA) provided a list of major and minor defining characteristics of urinary retention (Doenges & Moorhouse, 1996). Major characteristics were identified as bladder distention and the absence of urine output or the presence of small, frequent voidings. Minor characteristics included a sensation of bladder fullness, dribbling, dysuria, overflow incontinence, and residual urine. NANDA did not quantify the volume of residual urine that the bladder must contain, however amounts ranging from 100 ml to over 500 ml have been suggested (Anderson & Grant, 1991; Doenges & Moorhouse, 1996; Tucker et al., 1995). Additional signs and symptoms associated with urinary retention include restlessness, diaphoresis (Phipps et al., 1995), anxiety, urinary frequency, fluid output less than intake (Tucker et al., 1995), and urgency (Holloway, 1993).

Authors generally differentiate postoperative urinary retention from other types of urinary retention by time of onset and situation, and not clinical signs and

symptoms. With respect to time, the postoperative period may be said to begin at the completion of the surgical procedure and end with discharge from medical care (Lewis, Collier, & Heitkemper, 1996). The postoperative period also may be limited to a specified time period following the completion of the surgical procedure, or in the case of urinary retention, to the time of catheterization. Some investigators (Anderson & Grant, 1991; Stallard and Prescott, 1988) limited the postoperative period in their studies to more than 12 hours after the induction of anesthesia, however others did not (Kemp & Tabaka, 1990; Tammela et al., 1986a; Walts et al., 1985; Wynd et al., 1996). Walts et al. (1985) reported the mean time to catheterization after hip arthroplasty in their study was 8.4 ± 4.5 hours. In studies with post general surgery patients, Kemp and Tabaka (1990) reported 65.5% (n = 61) required straight catheterization in the postanesthesia care unit, yet Tammela et al. (1986b) reported 90.5% of catheterizations in their study occurred six or more hours after the termination of surgery.

Assuming the absence of pre-existing urinary pathologies, the development of postoperative urinary retention is most often attributed to mechanical obstruction or functional alterations in neuromuscular control mechanisms. Mechanical obstruction is frequently attributed to local trauma and/or swelling of urinary and pelvic structures (Phipps et al., 1995) and high urethral pressure (Doenges & Moorhouse, 1996). Altered bladder tone and altered perceptions of bladder fullness are associated with

anesthetic agents (Michelson et al., 1988); sympathetic nervous system stimulation from pain, fear, and anxiety (Ulrich, Canale, & Wendell, 1994); and medications with adrenergic stimulating or cholinergic blocking effects (Kemp & Tabaka, 1990; Tammela et al., 1986a).

Contributing Factors

The majority of retrievable research examining factors related to the development of postoperative urinary retention were descriptive studies with inherently limited control of extraneous variables. Even though these studies identified a variety of different factors that had the potential to influence the development of postoperative urinary retention, the discussion of contributing factors is limited to those factors selected as contextual and residual stimuli for this study.

Age.

The findings for age related risk for development of postoperative urinary retention are not consistent across studies, even though age related changes in urinary structure and function are known to occur (Phipps et al., 1995). Females over the age of 60-65 years were reported to have an increased incidence of postoperative urinary retention (Michelson et al., 1988; Tammela et al., 1986a), yet no correlation between age and the incidence of postoperative urinary retention was documented by others (Hozack, Carpinello, & Booth, 1988; Stallard & Prescott, 1988; Walts et al., 1985).

Fluid intake.

Fluid intake has consistently been reported to influence the development of postoperative urinary retention. Perioperative fluid intake in excess of 1000 cc has been correlated with an increased incidence of postoperative urinary retention following orthopedic (Michelson et al., 1988; Wynd et al., 1996), anorectal (Petros & Bradley, 1991) and general surgeries (Kemp & Tabaka, 1991; Tammela et al., 1986a). Tammela et al (1986b) reported large volumes of intravenous fluids, large volumes of urine retained in the bladder (>500 cc), and increasing age were significant predisposing factors for prolonged voiding difficulties, repeat catheterizations, and prolonged hospitalizations.

Michelson et al. (1988) did not include fluid intake as a study variable, but confirmed a relationship between urinary retention volume (>700 cc) and subsequent bladder dysfunction necessitating indwelling catheterization. Although perioperative fluid restriction to 500 cc or less in patients undergoing anorectal surgeries was associated with a reduced incidence of postoperative urinary retention in several studies (Bailey & Ferguson, 1976; Bowers et al., 1976; Campbell, 1972), this approach to perioperative fluid administration is not always feasible or appropriate.

Medication use.

A variety of medications are known to have the potential to affect lower urinary function. For example, belladonna alkaloids, synthetic preparations of atropine

(e.g., methantheline and propantheline), oxybutynin, and dicyclomine hydrochloride may cause urinary retention (Fuselier, 1993). In addition, antihistamines, psychotropics, levodopa, and agents with alpha- or beta-adrenergic effects may influence lower urinary function as well (Stanton, 1978). Patients taking medications that could affect bladder function were excluded in one study (Stallard & Prescott, 1988) yet, most researchers do not address medication usage in sample characteristics and study design, with the notable exception of anesthetic agents and opioid analgesics.

Several researchers (Stallard & Prescott, 1988; Walts et al., 1985; Wynd et al., 1996) have studied the effect of opioid medications on the development of postoperative urinary retention. Opioid drugs, and in particular morphine sulfate, have been found to increase internal urinary sphincter pressure, diminish bladder sensations (Durant & Yaksh, 1988), and reduce bladder contractions (Dray & Metsch, 1984; Durant & Yaksh, 1988) in animal models. In addition, the sedative effects of morphine are thought to mask the pain of an over distended bladder and contribute to the development of painless urinary retention (Hommeril, Bernard, Gouin, & Pinaud, 1994). Wynd et al. (1996) found a significant increase in the urinary retention rates for subjects in a pilot study (N = 50) who received morphine as a postoperative analgesic agent as compared to those subjects who did not receive morphine, but the results of a second, larger study (N = 205) did not confirm or refute this relationship.

The use of morphine analgesia was not controlled for in the second study and investigators were hesitant to promote or discount morphine as a potential risk factor for the development of postoperative urinary retention.

Stallard and Prescott (1988) reported a significantly higher rate of postoperative urinary retention with opiate analgesia by intravenous infusion than with intramuscular bolus injection ($p < 0.05$, $N = 280$). Walts et al. (1985) reported epidural morphine usage was associated with an increase incidence of postoperative urinary retention from 24% to 62 % ($N = 272$). The findings from these two studies were incongruent with Tammela et al.'s (1986b) report that the type of medication used for postoperative analgesia had no significant effect on urinary retention rates ($N = 5,220$).

Type of surgery.

Identification of a patient's risk for the development of postoperative urinary retention according to the type of surgery performed is difficult. In part, this difficulty stems from the necessary exclusion of postoperative patients who have had an indwelling urinary catheter placed before or during the surgical procedure. The majority of available research reports detail investigations of specific postsurgical populations with a presumed increased risk of developing postoperative urinary retention, such as patients undergoing orthopaedic or anorectal surgeries. Although these populations may be at increased risk, only a few studies have compared the

relative risk for persons having different types of surgical procedures. In two studies involving general surgery patients, individuals undergoing abdominal surgeries (Stallard & Prescott, 1988), thoracotomies, and endoprosthetic hip and knee procedures (Tammela et al., 1986a) were identified as having a greater incidence of postoperative urinary retention than patients undergoing other types of surgeries such as those involving the head and neck.

Type of anesthesia.

Doyle and Briscoe (1976) studied the effects of selected drugs and anesthetic agents on urethral resistance and bladder capacity. These investigators reported that urethral pressure was lowered by anesthetic induction agents such as thiopentone, and raised by opiates. Furthermore, bladder capacity was greatly increased by halothane and diminished after administration of intravenous, but not intramuscular, diazepam. In studies involving postoperative patients, spinal anesthesia (Petros & Bradley, 1990), and epidural morphine (Waltz et al., 1985) were correlated with increased retention rates in some sample populations, but not in others (Michelson et al., 1988; Tammela et al., 1986a; Wynd et al., 1996). The difficulty in clearly identifying the potential contribution of the type of anesthesia employed to the development of postoperative urinary retention is also compounded by the frequent administration of an opioid medication as one of the pharmacologic agents used to provide for patient anesthesia (V. Cassmeyer, personal communication, May 7, 1997).

Peppermint Oil

The documented use of peppermint oil for medicinal purposes dates back to Pliny and Hippocrates (Sigmund & McNally, 1969). Even though peppermint oil has been claimed to have therapeutic benefit in a myriad of different conditions, relatively few of these effects have been empirically studied and reported findings are inconsistent.

In vivo, controversy exists about the clinical effectiveness of peppermint oil in gastrointestinal usage. In an early study (Plant & Miller, 1926), peppermint oil and specifically menthol reduced the frequency and amplitude of GI contractions in canine subjects. In an investigation with human subjects almost five decades later, Sigmund and McNally (1969) performed a controlled study involving balloon manometry of the intraesophageal, intrasphincteric, and intragastric regions of the gastrointestinal tract in response to intragastric instillation of a dilute peppermint oil solution. Peppermint oil instillation resulted in cardiac sphincter relaxation and an equalization of esophageal and gastric pressures with gastroesophageal reflux in 25 of 27 subjects within one to seven minutes of administration.

Jarvis, Hogg, and Houghton (1992) reported peppermint oil was a safe, effective, and inexpensive alternative to intravenous agents for colon spasm during barium enema (N = 20). In a replication study (Sparks, O'Sullivan, Herrington, & Morcos, 1995), investigators reported significantly lower rates ($p < 0.001$) of colonic

spasm ($n = 141$). In addition, these investigators contended that although toxicological data were not available for peppermint oil used in this manner, subjects experienced no appreciable side effects.

Peppermint oil has also been employed in the treatment of irritable bowel syndrome. In two small clinical trials by Dew, Evans, and Rhodes (1984) ($n = 29$) and Rees, Evans, and Rhodes (1979) ($n = 33$) peppermint oil was reported to be generally well tolerated and effective for symptom control. In a later study (Nash, Gould, & Barnardo, 1986) of comparable size ($n = 41$), investigators failed to find compelling evidence of peppermint oil's effectiveness to diminish abdominal pain associated with irritable bowel syndrome.

Gobel, Schmidt, and Soyka (1994) tested the analgesic effects of topical applications of peppermint oil and eucalyptus oil preparations on the neurophysiological, psychological, and experimental headache parameters in 32 healthy subjects in a double-blind, placebo controlled, randomized cross-over design study. Results demonstrated peppermint oil in combination with ethanol and eucalyptus oil produced statistically significant difference in skeletal muscle relaxation, cognitive performance-related activity ($p \leq 0.001$) and concentration ($p \leq 0.05$). A combination of peppermint oil and ethanol had a statistically significant effect on muscle relaxation, mental relaxation, and reduced pain sensitivity ($p \leq 0.001$). Application of ethanol alone or in combination with eucalyptus oil did

not produce any statistically significant effects on the aforementioned experimental headache parameters.

In vitro, peppermint oil and menthol in particular have been shown to relax gastrointestinal smooth muscle cell preparations in animal (Hills & Aaronson, 1991; Hills, Potts, Carlin, & Parsons, 1990; Swandulla, Schafer, & Lux, 1986; Taylor, Luscombe, & Duthie, 1983) and human specimens (Taylor et al., 1985). The mechanism by which peppermint oil produces smooth muscle relaxation in each of these studies was purported to be by inhibition of extracellular calcium ion influx through ionic pores or channels in cell wall membranes. The ability of peppermint oil and menthol in particular to modulate the influx of extracellular calcium is postulated to be through alteration and not occlusion of pore gating mechanisms (Swandulla et al., 1986).

Voltage sensitive gating mechanisms control not only ion movement through pore channels, but access to receptor or blocking sites located within the pore channels (Hills & Aaronson, 1991; Yeh & Armstrong, 1978). Using single cell patch clamp techniques, investigators (Hills & Aaronson, 1991) found that peppermint oil inhibited depolarization-mediated and agonist-mediated smooth muscle contraction by altering calcium influx through the voltage sensitive or potential-dependent channels. As calcium influx through ionic channels is intimately related to the release of neurotransmitters and muscle function (Reuter, 1983), any disruption of calcium

dependent processes by peppermint oil could have important functional significance for the parent organ structures. Although the effects of peppermint oil have been studied in a variety of animal and human tissues, no reports of laboratory testing specific to urinary smooth muscle were found.

Summary

Researchers are in agreement that the etiology of postoperative urinary retention is most likely multifactorial, but differ as to the level of significance ascribed to individual or combinations of predisposing factors. This lack of investigator consensus may be in large part related to the complex nature of lower urinary tract function and differences in sample characteristics and study design. Peppermint oil has been shown to affect calcium dependent cellular processes and neurotransmitter release in muscle tissues in laboratory testing and investigators have reported on the therapeutic benefits of peppermint oil use in gastrointestinal disorders and radiologic procedures. It is possible based upon these study results that peppermint oil may have an effect on urinary structures and function, but no conclusive scientific evidence to support the use of peppermint oil for patients experiencing postoperative urinary retention was found.

Chapter 3

Methodology

The study methodology, including the research design and description of the sample and settings, is presented in this chapter. A description of the developed instrument and intervention protocol is presented. Ethical considerations, the procedure used for data collection, and data analysis are described.

Research Design

A descriptive correlational study design was planned to investigate the use of peppermint oil as a nursing measure for adult women experiencing postoperative urinary retention and to answer three research questions. The study design was later modified to a comparative descriptive design because the sample size was insufficient to perform correlation statistical tests.

Settings and Sample

Selected surgical units in two Midwest health care facilities served as the study settings. The first facility, Hospital A, is a 178 bed hospital in east central Kansas. Hospital A is located in a rural city of over 29,000 that provides health care services to over 60,000 persons (J. DeDonder, personal communication, May 27, 1997). The second facility, Hospital B, is a regional medical center located in eastern Kansas. Hospital B is a university-affiliated, tertiary care center.

The nine surgical units selected for use in this study routinely admit patients for a variety of surgical procedures and provided for diversity in sample characteristics. One nursing unit was selected for use in Hospital A. During the course of the study, a same day surgery unit and a second nursing unit were added at Hospital A to increase the accessible population. Five surgical nursing units and a same day surgery unit and were selected for use in Hospital B.

The convenience sample in this study was comprised of females, 18 years or older, scheduled for an elective surgery. Patients scheduled for non-elective surgeries were included if the consent process did not cause undue stress or delay in preoperative preparation. Subjects were enrolled from August 20, 1997 to January 7, 1998.

The investigator identified potential subjects by reviewing the surgery schedule posted in the surgical unit. Potential subjects' charts were reviewed by the investigator for the presence of exclusion criteria. Potential subjects were excluded if they: a) were male, b) did not have attending surgeon approval, c) were scheduled for surgery of the urinary tract, d) had an indwelling urinary catheter, e) had a written physician order to insert an indwelling urinary catheter, f) were scheduled for admission to an intensive care unit after surgery, or g) had a known allergy to peppermint oil or menthol. In addition, all potential subjects were required to be able to read and speak English.

The original plan was for the investigator to enroll potential subjects until a minimum number of 10 subjects who voided after peppermint oil administration and 10 subjects who did not void after peppermint oil administration were obtained. At the end of five months, the sample consisted of four subjects who had experienced peppermint oil administration. Subject recruitment was terminated.

Instrument

Existing instruments related to the study concepts were not found. A new instrument, the Postoperative Urinary Retention Assessment (PURA), was designed by the investigator for data collection in this study (Appendix A). The two part PURA instrument was developed in accordance with select tenets of the Roy Model and the literature review. A panel of content experts, comprised of three doctorally prepared nurses, then evaluated the instrument for appropriateness, accuracy, and relevance to the theoretical framework and problem under investigation.

The PURA instrument format and content were revised by the investigator based upon the input provided by members of the content expert panel. Format changes were made to facilitate orderly data collection and documentation. Content revisions were made to improve the instrument's ability to accurately and appropriately measure contextual and residual stimuli data.

The instrument was piloted with the first study subject. Based upon the results of the instrument pilot test, no further revisions in the PURA instrument were made.

As no changes were made in the instrument after the pilot test, the subject was retained in the sample and included in data analysis. Discussion of the data recorded on each part of the PURA instrument, the process for recording data, and the content revisions made as a result of content expert panel review follows.

PURA - Part A.

The PURA - Part A was designed to document data related to study criteria, contextual (age, fluid intake, medication use) and residual stimuli (type of surgery, type of anesthesia) selected for use in this study. Apart from age, no other demographic data, such as race/ethnicity, religious preference, income, or education, was included on the instrument. Subject allergy information was obtained from chart records and verbally verified with the subject by the investigator. The subject's chart record number was recorded on the instrument for the sole purpose of chart retrieval and data confirmation, if needed by the investigator.

The date of birth documented on the subject's hospital admission record was used to determine subject age. Data obtained from chart records was used to calculate the subject's fluid intake in milliliters for the time period between the start of the surgical procedure and until the determination of postoperative urinary retention was made by a registered or licensed practical nurse staff member employed by the hospital. Fluid intake was operationally defined as the sum total of oral, parenteral,

irrigation, and instillation fluids administered to the subject. Parenteral intake included crystalloid solutions, colloid solutions, and blood and blood products.

Medication use data obtained from chart records was recorded on the instrument for all medications administered to the subject during the perioperative period. The perioperative period was limited to the time period beginning two hours prior to the start of the surgical procedure and ending when the determination of postoperative urinary retention was made by a licensed staff nurse. The perioperative period was subdivided on the instrument into the preoperative, intraoperative, and postoperative periods. All medications given within two hours of the surgery start time were recorded as preoperative medications. All medications administered during surgery were recorded as intraoperative medications. All medications administered from the end of surgery and until the time that postoperative urinary retention was determined by the licensed staff nurse were recorded as postoperative medications. The surgery start and end times were obtained from the intraoperative records.

All medications administered to the subject, regardless of route of administration or intended therapeutic effect, were documented on the PURA - Part A. Specific medication use data recorded on the instrument included the medication's name, dose, route, and time of administration. In addition, the sum total number of the different medications administered during the perioperative period was recorded.

Based upon content expert recommendation, the instrument was revised to provide for documentation related to medications with a known side effect of urinary retention. The sum total of different medications and the number of total doses of these medications with a known side effect of urinary retention that were administered to the subject were recorded. Each medication recorded on the instrument was checked by the investigator with the drug profile information printed in a 1996 edition of Drug Facts and Comparisons to determine if a side effect of urinary retention existed or not.

Data for the selected residual stimuli were also recorded on the PURA - Part A. The type of anesthesia administered to the subject and the type of surgery performed were obtained from the intraoperative records. The type of anesthesia was documented as either general or non-general.

The original form of the PURA - Part A provided for documentation of a third residual stimuli, opioid analgesics. Based upon input from the content expert panel, specific reference to opioid analgesics was deleted. The rationale for this modification was that opioid analgesics were subsumed within the contextual stimuli, namely medication use, and did not represent a distinctly separate residual stimuli. Space was added to document whether or not a subject voided, the time of voiding, and the time postoperative retention was determined by licensed nursing staff.

PURA - Part B.

The PURA - Part B was designed to record data pertaining to the context of and subject response to peppermint oil administration. The context of peppermint oil administration included nursing and environmental data. The licensed nurse was asked to recall the actions/assessments used to make a determination that the subject was experiencing postoperative urinary retention and the measures used to promote subject voiding. These data were obtained by the investigator and recorded on the instrument as provided by the licensed nursing staff member. Data related to the environmental context included such information as the time and location of the voiding attempt, subject position, and the urine collection device used. Environmental data were obtained through direct observation of the environment by the investigator.

The PURA - Part B also included data related to the subject's response to peppermint oil administration. The investigator performed and documented two assessments of the subject's response to peppermint oil administration on the instrument. The first assessment was performed immediately following peppermint oil administration and the second assessment was performed approximately 24 hours later. Assessment information documented on the instrument included the subject's response to three questions pertaining to the presence or absence of symptoms associated with an adverse reaction to peppermint oil and a physical assessment of the condition of subject's perineal tissues.

Due to the possibility of a subject being dismissed from the hospital prior to the investigator personally performing the physical assessment at the 24 hour follow up assessment, the procedure was modified. The modification allowed the investigator to obtain a subject self-report on the condition of perineal tissues during a telephone interview as opposed to conducting the assessment in person. The Human Subjects Committee was notified of the modification in procedure and the subject consent form was amended accordingly.

Intervention

A Peppermint Oil Administration Protocol (POAP) was developed by the investigator to establish guidelines for the preparation and administration of peppermint oil. This protocol was developed from analyses of available literature and input from three registered nurses experienced in peppermint oil use. The POAP was piloted with the first study subject and the first subject who experienced urinary retention. Based upon the pilot test results, the POAP was found to be appropriate for use and no modifications were made. As no modifications were made in the POAP following the pilot test, the two subjects were included in the sample and data analysis. The POAP was implemented on each date that data collection was performed.

The peppermint oil U.S.P. was obtained from a local pharmacy outlet. Pharmaceutical products labeled U.S.P. have an established standard for source,

physical and chemical properties, purity and identity, and assay of the product (Kozier et al., 1995). A sample copy of the POAP with rationales is presented in Appendix B.

Ethical Considerations

Permission for the study was obtained from the Institutional Review Board at the University of Kansas Medical Center on July 22, 1997 (Appendix C). All female patients identified as eligible potential subjects were approached by the investigator to obtain consent for study participation. The only exceptions were female patients who had already agreed to participate in another research study in progress at Hospital B.

Each subject was required to read the consent form explaining the purposes of the study, assuring them of anonymity, and requesting voluntary cooperation prior to participation. Subjects were informed that the use of noninvasive nursing measures to stimulate voiding is the usual initial treatment for postoperative urinary retention and that their participation in the study would not unduly prolong or alter the course of events in established treatment routines. Furthermore, subjects were informed that the physical and psychological risks for participation in this study were comparable to those that could be reasonably anticipated with any episode of postoperative urinary retention. The potential risks specific to the use of peppermint oil included the risk for local irritation of perineal tissues and any unpleasantness associated with inhalation of peppermint oil vapors. Potential benefits included successful voiding with the

implementation of nursing actions and no immediate need for further treatment measures to promote urine elimination.

Subjects were informed that they could have access to study results by contacting the investigator. There were no additional financial costs incurred by the subject for participation in the study, and all costs associated with the study were paid for by the investigator. All copies of the PURA instrument will remain in a locked file in the possession of the investigator, until destroyed. A copy of the informed consent form is presented in Appendix D.

Procedure

The procedure for data collection in this study required the approval of hospital administration and surgeons prior to investigator approach of eligible potential subjects. The procedure for data collection is illustrated in Figure 1. A description of the procedure follows.

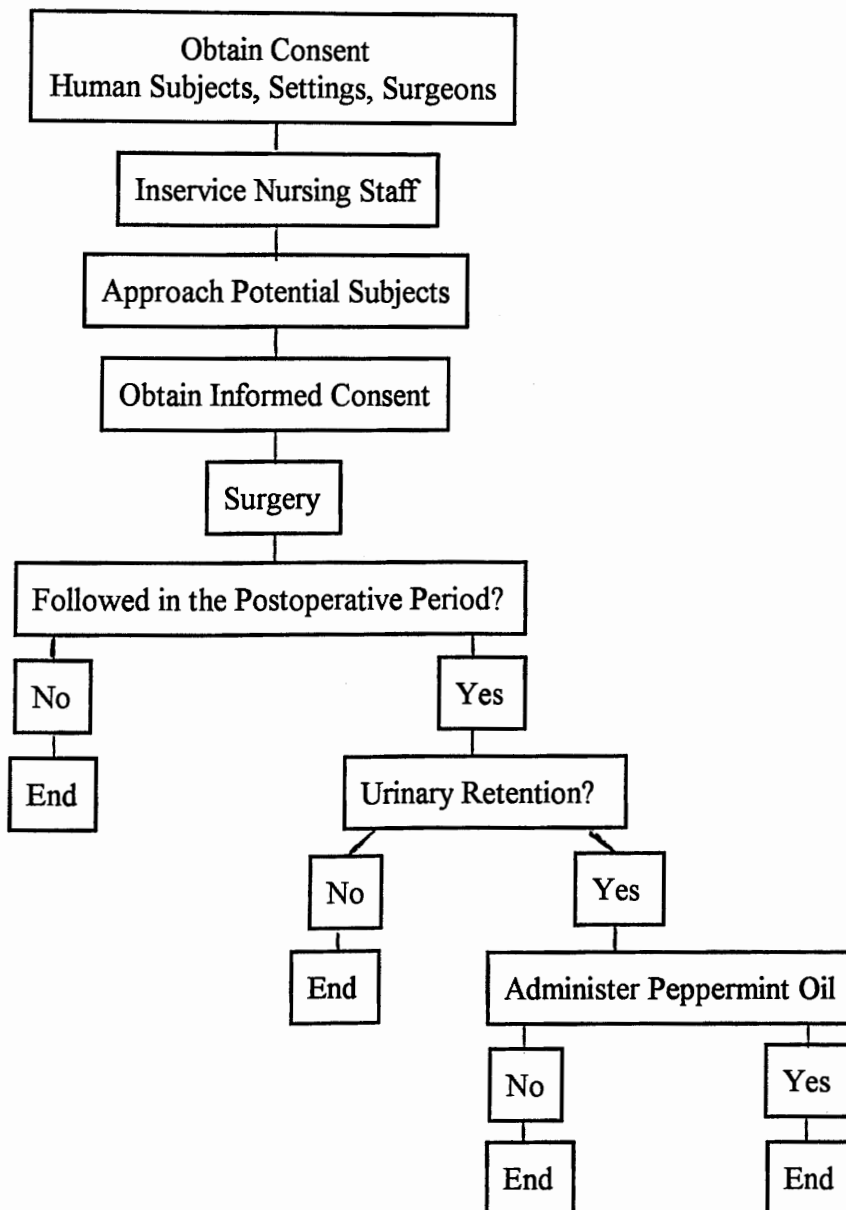


Figure 1.

Study procedure.

Hospital approval.

Approval to conduct the study was sought at Hospital A and Hospital B. The Assistant Administrator and Clinical Director at Hospital A granted approval to conduct the study following approval by the multidisciplinary Leadership Group and by the urologist who practices in the community. The Assistant Administrator at Hospital A later requested that two additional modifications in procedure be accommodated by the investigator. The first modification was that the investigator would contact the local medical doctors with hospital privileges to inform them of the planned study. The second modification was that a physician's order for the "Peppermint Oil Protocol" be written on the physician's order sheet in study subject's chart postoperatively.

The request by the Assistant Administrator at Hospital A for modifications were accommodated by the investigator. Letters were distributed to the local medical doctors to inform them of the study and directing them to contact the investigator if they had any questions or concerns related to the study. It was mutually agreed upon by the Assistant Administrator, the surgeons whose patients would be potential study subjects, and the investigator that the investigator could transcribe an order for "Peppermint Oil Protocol" on the subject's chart after informed consent was obtained. The order was to be documented as a verbal order from the physician to the

investigator. The surgeon would then be responsible for following established hospital procedure for consigning the verbal order.

The Associate Administrator at Hospital B granted approval to conduct the study following the Nursing Research Council review and approval of the study proposal. Copies of the written approval from clinical agency personnel (Appendix E) and a sample letter sent to medical physicians at Hospital A (Appendix F) are provided.

Surgeon approval.

A total of 42 surgeons were contacted by the investigator to seek approval to approach the patients under their care. The investigator, with input from hospital staff, initially identified 30 surgeons who admitted patients to the selected surgical units. The investigator contacted these surgeons in writing to inform them of the proposed study and to seek permission for the investigator to approach their patients. Approval to approach patients under their care was given by 21 of the 30 surgeons. As data collection proceeded, it became apparent that the accessible population of subjects generated by these surgeons was not adequate to accomplish data collection in a time effective manner. The investigator contacted an additional twelve surgeons, six of whom granted approval to approach their patients. A sample copy of the physician consent form is provided (Appendix G).

Nursing staff inservice.

After approval to approach patients was obtained from surgeons and hospital administrators, the investigator scheduled staff inservice meetings with the clinical directors and/or unit nurse managers. The staff inservice meetings were designed to provide licensed nursing staff with information about the study and to explain the process used to notify the investigator when a study subject was experiencing postoperative urinary retention. Based upon the request of clinical directors and nurse managers, all licensed and unlicensed nursing staff members were included in the staff inservice meetings. Nursing staff members were given a copy of the Nursing Staff Information Sheet detailing the process of investigator notification. All absent nursing staff members were provided with written information about the study and afforded the opportunity to contact the investigator. In response to nursing staff members' requests, a copy of the Nursing Staff Information Sheet was posted in the surgical units. A sample copy of the Nursing Staff Information Sheet is provided (Appendix H).

Data collection.

The investigator approached eligible potential subjects in the surgical unit on the morning of surgery to explain the purposes of the study and obtain consent for study participation. The investigator approached patients at a time that did not interfere with scheduled preoperative treatments or procedures, and prior to the

administration of any preoperative narcotic, sedative, or hypnotic medications. After subject consent was obtained, the subject was given an identification number corresponding to the rank order in which they entered the study. A copy of the Nursing Staff Information sheet was placed in the chart for staff reference and a self-adhesive sticker (Appendix I) was affixed to the front of the chart cover to indicate patient participation in the study. Data collection with the PURA instrument was initiated.

The investigator was responsible for all data collection and documentation related to the PURA instrument. Any subject who did not experience postoperative urinary retention had only chart number, allergy, age, type of surgery, type of anesthesia and time of voiding data recorded on the PURA - Part A. Data collection for subjects who developed postoperative urinary retention continued on the PURA instrument until the final assessment of patient response to peppermint oil administration was performed by the investigator on the next day, approximately 24 hours after peppermint oil administration.

Upon the patient's transfer to the surgical unit after surgery, the investigator recorded the start and stop time for the 12 hour postoperative period on the sticker affixed on the front of the subject's chart. This sticker notified licensed nursing staff of the time period in which the investigator should be notified in the event that the subject developed postoperative urinary retention. The licensed nursing staff member

assigned to the subject was responsible for providing the routine and customary postoperative nursing care and for the determination of whether or not a subject had developed postoperative urinary retention. No attempt was made by the investigator to control the nature of the routine and customary care provided by the nursing staff. In addition, no attempt was made by the investigator to control the number or type of nursing actions/assessments used by the nursing staff member to promote voiding or to determine that the subject was experiencing postoperative urinary retention.

The investigator periodically checked on the subject's status throughout the timed postoperative period to ascertain if voiding had occurred. When a licensed staff nurse had determined that the subject had developed postoperative urinary retention, the nurse notified the investigator by pager as soon as possible. The investigator promptly responded and informed the licensed staff nurse whether or not the investigator could arrive at the subject's bed side within five minutes. If the investigator was unable to arrive at the subject's bed side within five minutes, subject participation was terminated.

Upon arrival at the subject's bed side, the investigator placed a test dose of peppermint oil into the subject's urine collection container (bed pan, commode, in-toilet collection device). The investigator assisted the nursing staff member as needed to position the subject on the urine collection device. As soon as the subject was positioned on the urine collection device, the investigator began timing of the

5-10 minute test period with a stop watch. The timing period was limited to 5-10 minutes to reduce subject fatigue and possible discomfort. No purposeful attempt was made to prevent the subject from inhaling the peppermint oil vapors. The time the treatment period started, the amount of oil administered, and the time that the oil was administered was recorded on the PURA - Part B.

During the time period that the peppermint oil was being administered, the nursing staff member in attendance was instructed not to perform any additional measures to promote voiding. This restriction was necessary to limit the introduction of extraneous variables that could have an effect on the subject's response to the peppermint oil treatment. The investigator recorded data related to the environment on the PURA - Part B. The investigator asked the licensed nurse assigned to the subject to recall the actions/assessments that led to the determination of postoperative urinary retention and the nursing measures that were implemented to promote voiding prior to the investigator's arrival. The investigator recorded the nurse's response to these two questions, as it was provided by the nurse on the PURA - Part B. The investigator made no purposeful attempt to elicit information to determine completeness or accuracy of the nurse's response.

At the end of the timed peppermint oil administration period, after care was provided in accordance with the POAP by the nursing staff and/or investigator. The investigator performed and documented an assessment of the subject response to

peppermint oil administration. After this initial assessment was performed, the nursing staff were responsible for resuming the usual and customary postoperative patient care. A second assessment was performed and documented by the investigator approximately 24 hours later. After the second assessment was performed by the investigator, subject participation in the study was terminated.

Data Analysis

Numerical data related to the contextual and residual stimuli were extracted from the PURA, coded, and entered into a computer data base. Data for all contextual and residual stimuli were analyzed using descriptive statistical tests contained in the Statistical Packages for the Social Sciences (SPSS) computer software program. To facilitate analysis and reporting of the data, subjects were grouped according to voiding ability and response to peppermint oil administration.

Group 1 subjects did not develop postoperative urinary retention during the first 12 hours after surgery. Subjects who experienced postoperative urinary retention were included in Group 2 or in Group 3 based upon their response to the administration of peppermint oil. Subjects who voided after the administration of peppermint oil were in Group 2. Subjects who did not void after the administration of peppermint oil were in Group 3. Specific descriptive tests used for each research question, and the method used to report data related to the context of peppermint oil administration follow.

Research question 1.

The research question “What is the difference between adult women who do and do not develop postoperative urinary retention with regard to selected contextual (age) and residual stimuli (type of surgery, type of anesthesia)?” was answered using descriptive statistics. Age data from Group 2 and Group 3 were collapsed and compared in table form to the data from Group 1. Age was reported as a range, mean, median, standard deviation, and frequency distribution.

Residual stimuli (type of surgery, type of anesthesia) data for Group 2 and Group 3 were also collapsed and compared to Group 1 data. Type of surgery was coded by the body region primarily involved in the surgical procedure and entered into the data base. The data were coded as head and neck, abdominal, inguinal and anorectal, and extremity. Type of anesthesia was coded as either general or non-general and entered into the data base. Data were reported in a table format as frequency and percent.

Research question 2.

To answer the research question “What is the difference between women with postoperative urinary retention who do and who do not void after the administration of peppermint oil with regard to selected contextual stimuli (age, fluid intake, medication use)?”, a table was constructed to compare the data from each individual subject in Group 2 and Group 3. This approach was used given the small number of

subjects in each of the two groups. Age was reported in years, fluid intake as the sum total number of milliliters administered, and medication use data as frequencies.

Research question 3.

The research question “What is the difference between women with postoperative urinary retention who do and who do not void after the administration of peppermint oil with regard to selected residual stimuli (type of surgery, type of anesthesia)?” was answered individually for each subject in group 2 and in Group 3 in narrative form. The age, surgical procedure, and type of anesthetic administered were described. The duration of surgery in minutes was calculated from the surgery start and end times recorded on the PURA - Part A. The range, mean, and standard deviation for the duration of surgery were calculated and reported.

Context of administration.

The context of administration included data recorded on the PURA instrument related to the nursing and environmental context in which the peppermint oil was administered. The number of minutes elapsed from administration of peppermint oil to voiding response was calculated for each subject in Group 2. Data related to the nursing and environmental context for peppermint oil administration were reported as a narrative description. Data related to the two follow up assessments of subject response to peppermint oil administration were also reported as narratively.

Summary

A comparative descriptive research design was used to investigate the use of peppermint oil as a nursing measure for adult women experiencing postoperative urinary retention in a convenience sample of women, age 18 years and older, at two Midwestern health care facilities. The POAP served as the standard for peppermint oil administration. In order to answer the three research questions, the data extracted from the newly developed PURA instrument was coded, entered into a computer data base, and analyzed using descriptive statistics.

Chapter 4

Results

In this chapter, study findings are presented. The findings related to surgeon approval, nursing inservice, and sample characteristics are reported. Findings related to the three research questions, the context of peppermint oil administration, and limitations of the study are presented.

Surgeon Approval

A total of 42 surgeons were contacted by the investigator to seek approval to approach patients under their care. Of the 42 surgeons contacted, seven out of nine (78%) surgeons at Hospital A granted approval, two (22%) declined approval. At Hospital B, 21 of 33 (64%) granted approval, 5 declined approval (15%), and 7 (21%) did not return the consent form. Follow up attempts by the investigator to have these seven surgeons complete and return the consent form were unsuccessful. Consenting surgeons represented of a variety of surgical practices: general surgery, with or without a designated specialty area; vascular; orthopedics; obstetrics and gynecology; and, ear, nose and throat. Summary statistics for surgeon approval are presented in Table 1.

Table 1.

Surgeon Response by Type of Practice and Setting

Response	<u>Hospital A (n = 9)</u>		<u>Hospital B (n = 33)</u>			<u>Total (N = 42)</u>		
	Yes	No	Yes	No	NR	Yes	No	NR
Type of Practice								
General Surgery	1	1				1	1	0
General/Oncology			1	1	1	1	1	1
General/Transplant			1	1		1	1	0
Vascular	1		2		1	3	0	1
Orthopedics	3		4	2	1	7	2	1
Obstetric/Gynecology	2	1	6		1	8	1	1
Ear, Nose & Throat			7	1		7	1	0
Plastic/Reconstructive					3	0	0	3
Total	7	2	21	5	7	28	7	7
(%)	(78)	(22)	(64)	(15)	(21)	(67)	(17)	(17)

NR -no response

Due to rounding, percentages may not equal 100.

Nursing Staff Inservice

The investigator provided scheduled staff inservice to 26 nursing staff members at Hospital A and 65 nursing staff members at Hospital B. Written

information was provided to 23 nursing staff members at Hospital A and 79 nursing staff members at Hospital B. A number of nurses at both hospital settings who were unable to attend a scheduled staff inservice meeting later approached the investigator to discuss the study and review the process for investigator notification.

Sample Characteristics

A total of 92 qualified potential subjects were identified from review of the surgical schedules at Hospital A and Hospital B. Of these potential subjects, 73 (79.3 %) consented to participate in the study. The sample consisted of 22 subjects (30%) from Hospital A and 51 subjects (70%) from Hospital B. The reasons for nonparticipation most often reported by potential subjects included a belief that they would have no difficulty voiding after surgery, and/or a perception that study participation would unduly increase feelings of stress experienced during the perioperative period.

In the postoperative period, 25 subjects (34.2%) were lost to follow up. Subjects lost to follow up were either dismissed from the hospital prior to determining ability to void successfully after surgery ($n = 16$), or had an indwelling urinary catheter in place postoperatively ($n = 9$). All of the subjects dismissed prior to voiding were classified on the surgery schedule as either outpatients or same day surgery patients. Of the of remaining study subjects ($n = 48$), age ranged from 18 to 81 years with a mean of 44.2 years ($SD = 17.59$).

Subjects ($n = 44$, 92%) who were able to void successfully in the postoperative period were placed in Group 1. Four subjects (8%) developed postoperative urinary retention. Of these four subjects, the three subjects who voided after the administration of peppermint oil by the investigator were placed in Group 2. The one subject who did not void after peppermint oil administration was placed in Group 3. All four cases of postoperative urinary retention occurred at Hospital B.

Research Question 1

To answer the question “What is the difference between adult women who do and do not develop postoperative urinary retention with regard to selected contextual (age) and residual stimuli (type of surgery, type of anesthesia)?”, descriptive statistical tests were performed on data extracted from the Postoperative Urinary Retention Assessment (PURA) - Part A. Data from subjects in Group 1 were compared to the collapsed data from subjects in Group 2 and Group 3.

Subjects who developed postoperative urinary retention ($n = 4$) ranged in age from 21 to 64 years with a mean age of 34 years ($SD = 20.11$ years). The age of subjects who did not develop postoperative urinary retention ($n = 44$) ranged from 18 to 81 years with a mean age of 45.2 years ($SD = 17.30$ years). Summary statistics for the contextual stimuli age are presented in Table 2.

Table 2.

Comparison of Age and Incidence of Urinary Retention

	Retention (n = 4)	No retention (n = 44)	Total (n = 48)
Age in years			
18 - 20		7	7
21 - 30	3	1	4
31 - 40		8	8
41 - 50		15	15
51 - 60		5	5
61 - 70	1	3	4
71 - 80		3	3
81 - 90		1	1
Mean	34	45.2	44.2
Median	25.5	42	41
Standard deviation	20.11	17.30	17.59
Range	21 - 64	18 - 81	18 - 81

Residual stimuli specified in research question 1 were type of surgery and type of anesthesia. The type of surgery performed on subjects was classified according to the body region primarily involved in the surgical procedure. The classifications used were head and neck, breast, abdominal, and extremity. Abdominal surgeries included

laparoscopy, dilatation and curettage (D&C), and colonoscopy. Surgeries on an extremity were all orthopedic procedures with the exception of one, a vein stripping and ligation. The type of surgeries performed on study subjects ($n = 48$), in descending order of frequency, were extremity, abdominal, head and neck, and breast. Of the subjects in Group 1 ($n = 44$), 26 had surgery involving an extremity, 9 an abdominal surgery, 8 a head and neck procedure, and 1 a breast surgery. Three out of four subjects with urinary retention (Group 2 and Group 3 combined) had an orthopedic surgery performed on an extremity. One subject had surgery involving the head and neck.

The type of anesthesia was classified as either general or non-general. All subjects in Group 2 and 3, and the majority of subjects in Group 1 (68%) received a general anesthetic. Summary statistics for the residual stimuli are presented in Table 3.

Table 3.

Comparison of Residual Stimuli and Incidence of Urinary Retention

	Retention (n = 4) Frequency (%)	No retention (n = 44) Frequency (%)	Total (n = 48) Frequency (%)
Type of surgery			
Head & neck	1 (25%)	8 (18%)	9 (19%)
Breast		1 (2%)	1 (2 %)
Abdominal		9 (21%)	9 (19%)
Extremity	3 (75%)	26 (59%)	29 (60%)
Type of anesthesia			
General	4 (100%)	30 (68%)	34 (71%)
Non-general		14 (32%)	14 (29%)

Research Question 2

To answer the research question “What is the difference between women with postoperative urinary retention who do and who do not void after the administration of peppermint oil with regard to selected contextual stimuli (age, fluid intake, medication use)?”, data obtained from the PURA - Part A were analyzed using descriptive statistics. Given the small total number of subjects in Group 2 and Group 3, findings related to fluid intake and medication use were calculated and reported separately for each individual subject. Subjects in Group 2 (n = 3) and Group 3

(n = 1) were numbered consecutively, one through four, to facilitate presentation of findings.

The mean age of subjects in Group 2 was 38.3 years (SD = 22.23). The one subject in Group 3 was 21 years old. Fluid intake in milliliters for subjects in Group 2 and Group 3 ranged from 1590 to 3724 with a mean of 2431 (SD = 1007.15). The majority of fluids received were administered intravenously during surgery. No colloid solutions, blood, or blood products were administered to any one of the four subjects. Subject 4 consumed 400 ml of fluid by mouth and Subjects 1, 2, and 3 consumed 25 ml or less prior to the determination of postoperative urinary retention.

Medication use data were calculated for the sum total of different medications administered, and the sum total of different medications with a side effect of urinary retention and the total number of doses administered. All pharmacologic agents were included in the medication use calculations, regardless of route of administration or intended therapeutic effect. The number of different medications administered to subjects ranged from 13 to 18 with a mean of 16 (SD = 2.16). The number of different medications administered with a side effect of urinary retention ranged from 5 to 6 with a mean of 5.75 (SD = 0.50). The number of doses of a medication with a side effect of urinary retention ranged from 7 to 11 with a mean of 8.5 (SD = 1.91).

Subject 4 received the smallest number (5) of different medications with a retention side effect. Subject 2 and Subject 4 were the only two subjects for whom a

patient controlled analgesia (PCA) device was used in the postoperative period.

Subject 2 received 7 mg of morphine sulfate via PCA over 3.5 hours. Subject 4 received 15 mg of morphine sulfate via PCA over 9 hours. Subject 2 voided after the administration of peppermint oil, Subject 4 did not. Summary statistics for research question 2 are presented in Table 4.

Table 4.

Comparison of Response to Peppermint Oil Use and Contextual Stimuli

	Subject			
	1	2	3	4
Response to peppermint oil	Void	Void	Void	No Void
Age	26	25	64	21
Fluid intake in ml	1675	1590	2735	3724
Medication use				
Different medications	17	13	18	16
Medications with retention side effect	6	6	6	5
Doses of medication with retention side effect	7	9*	11	7*

* PCA delivery system used by subject. Total amount of medication administered via PCA counted as one dose.

Further analyses were performed with the medication use data recorded on the PURA - Part A to investigate the nature of the medications administered to the four subjects during the perioperative period. The medications recorded on the PURA - Part A were assigned to a particular pharmacotherapeutic classification and the frequency of administration was calculated. The assignment of a medication to a particular classification was made according to the drug profile information printed in a 1996 edition of Drug Facts and Comparisons. This text was the same standard reference used to determine whether or not a medication had a side effect of urinary retention, or not.

Medications from 19 different drug classifications were administered to the four subjects from 2 hours before the start of surgery and until a determination of postoperative urinary retention was made by a licensed nurse. The majority of medications were administered during the intraoperative period for all subjects except Subject 3. Eight of the pharmacotherapeutic classifications contained one or more medications with a known side effect of urinary retention. Summary data for the number of different medications administered to retentive subjects by pharmacotherapeutic classification are presented in Table 5.

Table 5.

Medication Use by Pharmacotherapeutic Classification

	Subject			
	1	2	3	4
Adrenergic Antagonist ^b			1	
Anesthetic ^{a, b}	6	5	2	4
Antianxiety ^b			1	
Antibiotic	3	1	2	3
Anticholinergic ^b	1	1		1
Antiemetic/Antivertigo ^b	1			
Antihistamine ^b				1
Bronchodilator ^b			1	
Cholinergic	1	1		1
Diuretic			1	
Estrogen			1	
GI Stimulant			1	
Hemostatic			1	1
Histamine H ₂ Antagonist	1	1	1	
Mineral/Electrolyte			1	
Muscle Relaxant		1	2	1
Narcotic Analgesic ^b	1	2 ^c	3 ^c	3
NSAID	1	1		1
Vasopressor	2			
Total	17	13	18	16

NSAID = Nonsteroidal anti-inflammatory drug

^a Includes local and general anesthetic agents^b One or more medications in this class have a known side effect of urinary retention^c Includes one dose of a combined narcotic and non-narcotic analgesic medication

Research Question 3

To answer the research question “What is the difference between women with postoperative urinary retention who do and who do not void after the administration of peppermint oil with regard to selected residual stimuli (type of surgery, type of anesthesia)?”, data obtained from the PURA - Part A were analyzed using descriptive statistics. Three subjects had an orthopedic procedure involving a lower extremity and the fourth had surgery of the head and neck. The 25-year-old subject had an open reduction, internal fixation of a calcaneus fracture. The 21-year-old subject had a gastrocnemius flap, split thickness skin graft, and irrigation and debridement of a left leg wound. The 26-year-old subject had an arthroscopy and lateral ligament release of the right knee. The 64-year-old subject had a total thyroidectomy. All four subjects received a general anesthetic.

The duration of the surgical procedure performed on each subject was calculated. This calculation was figured as the number of minutes elapsed from the surgery start time and until the end time recorded on the PURA - Part A. Duration of surgery ranged from 68 to 148 minutes with a mean 105 minutes ($SD = 33.71$). The 26-year-old subject had the shortest duration of surgery (68 minutes). The 21-year-old subject who developed postoperative urinary retention had the longest duration of surgery (148 minutes).

Context of Administration

The context of administration was analyzed to investigate the nursing and environmental context in which the peppermint oil was administered. Data for the context of administration was recorded on both parts of the PURA instrument.

The range of time elapsed from the surgery end time and until the time a licensed nurse made a determination of postoperative urinary retention was from 3 hours, 2 minutes to 11 hours, 15 minutes. The mean duration of time elapsed was 4 hours, 39 minutes (SD = 3 hours, 33 minutes). The longest elapsed time belonged to the one subject who did not void after the administration of peppermint oil. The licensed staff nurse reported that this subject had expressed an urge to void and had made at least four unsuccessful attempts to void prior to peppermint oil administration.

A straight catheterization procedure was performed by the nursing staff member for the subject that did not void approximately 30 minutes post peppermint oil administration. The urine returned was 200 ml. Of note was the fact that the staff reported to the investigator that this subject continued to have difficulty with urine elimination and did not void for 11 hours after the straight catheterization was performed. An indwelling urinary catheter subsequently was inserted with a 1250 ml urine return.

The nursing assessments/actions used by the licensed staff member to make a determination of postoperative urinary retention were determined by nurse self-report. Nurses reported to the investigator that all four subjects had an absence of urine output postoperatively. Additional data reported by the nurses were primarily in the form of subjective symptoms obtained by subject interview. Subjects reported to the nurses that they experienced an urge to void, a sense of urinary urgency, an inability to relax, and nausea. One subject reported having suprapubic tenderness to the attending nurse.

Nursing measures reported to have been used by the nursing staff to promote subject voiding prior to the administration of peppermint oil were verbal encouragement, privacy, elevation of the head of bed, adequate time, and positioning the subject for attempts to void. Nurses reported that subjects made no fewer than 2 attempts to void prior to notifying the investigator that postoperative urinary retention had occurred. Interestingly, one subject reported to the investigator that she had tried without success to stimulate voiding by pouring cold water from the bedside water pitcher over her perineum.

The investigator was able to arrive at the subject's bed side within 5 minutes in all cases of postoperative urinary retention. When the investigator arrived at the subject's bed side, a 0.5 ml test dose of peppermint oil was placed in a bedpan (3) or bedside commode (1). One subject was in a semi-Fowler's position with the head of

bed elevated approximately 30 degrees. The other three subjects were sitting upright either in bed (1), on a bedside commode (1), or on a bedpan placed on a chair at the bedside (1). The range of time in minutes from peppermint oil administration to void was 5 to 32 with a mean of 15 (SD = 14.8 minutes).

At the conclusion of the peppermint oil treatment period, after care was provided and the investigator performed the initial follow up assessment. A second follow up assessment was performed by the investigator approximately 24 hours later. The investigator performed three of the four follow up assessments in person. The investigator conducted the fourth assessment by telephone interview.

There was no evidence of adverse reactions at the initial or follow up assessments performed by the investigator. Three subjects reported that the peppermint oil smelled “good” and one subject reported having experienced a “cool sensation” in her perineal area. Although no subject reported a negative olfactory experience with the peppermint oil, the investigator and staff noted a very pungent odor associated with the 0.5 ml dose. All subjects were in a room by themselves, therefore no input from a room mate or visitor present in the room at the time of administration could be obtained. The investigator found it somewhat difficult to completely remove the peppermint oil from plastic urine collection devices. A lingering odor of peppermint oil was detected for some time after the device had been cleaned with soap and water.

Limitations

This study was specific to the experience of postoperative urinary retention in a convenience sample of adult female patients in two selected acute care settings, a rural hospital and a regional medical center. The findings were limited by the small number of subjects who experienced postoperative urinary retention.

Threats to internal validity in this study included nonrandomization, the subject's past experience with voiding difficulties; the type, number, and combination of nursing measures employed to promote voiding by the licensed nursing staff; and random irrelevancies in the environmental stimuli and setting (e.g., pain, anxiety, fatigue). Threats to construct validity in this investigation included possible subject apprehension about being evaluated, investigator presence; and the amount of peppermint oil administered.

Summary

The sample in this study (N=73) was obtained in two settings; a rural hospital (n = 22) and a regional medical center (n = 51). A total of 42 surgeons (67%) approved investigator approach of patients under their care. A total of 91 nursing staff members attended inservice meetings conducted by the investigator. Written information was provided to another 102 nursing staff members who were unable to attend a scheduled inservice meeting.

Of the total sample (N=73), 25 (34.2%) were lost to follow up. The majority of subjects (92%) voided successfully during the postoperative period. Three out of four subjects with postoperative urinary retention voided after peppermint oil administration.

In summary for research question 1, the mean age of subjects who developed postoperative urinary retention in this study was 11.2 years younger than the subjects who voided successfully in the postoperative period. With regard to residual stimuli, the majority of subjects in all three groups received a general anesthetic and underwent an orthopedic surgery on a body extremity.

For research question 2, the subject who did not void after the administration of peppermint oil was younger, had the largest fluid intake, and had the fewest number of different medications with a side effect of urinary retention administered during the perioperative period. The oldest subject received the largest total number of different medications and the largest number of medications from different drug classifications.

For research question 3, all subjects with postoperative urinary retention received a general anesthetic. The one subject who did not void after peppermint oil administration underwent an orthopedic procedure and had the longest duration of surgery. The subjects that voided after peppermint oil administration (n = 3) had surgery of the head and neck (1) or an orthopedic procedure (2).

With regard to the context of peppermint oil administration, licensed nursing staff used a number of assessments/actions to determine whether or not the subject had developed postoperative urinary retention. Of the subjects with postoperative urinary retention ($n = 4$), all had attempted to void at least twice and had no urine output. The investigator prepared and administered all test doses of peppermint oil in accordance with the POAP. The duration of time elapsed from the end of surgery and until the peppermint oil was administered averaged 4 hours, 39 minutes. No adverse reactions to peppermint oil administration were detected at the two follow-up assessments performed by the investigator. The 0.5 ml dose of peppermint oil was pungent and difficult to completely remove from plastic urine collection devices.

Chapter 5

Discussion

In this Chapter, a discussion of the study findings and significance, implications for nursing, and suggestions for further research are presented.

Findings and Significance

Depending on study design and sample characteristics, postoperative urinary retention is reported to occur in 3.8% to 62% of surgical patients (Tammela et al., 1986b; Walts et al., 1985). The incidence of postoperative urinary retention in this study (8%, $n = 4$) compared favorably to rates reported in two larger studies with general surgery patients (Tammela et al., 1986b; Stallard & Prescott, 1988) (3.8% and 6% respectively) but was notably less than the rate reported in one other (Kemp & Tabaka, 1991) (61%).

Researchers concur that the etiology of postoperative urinary retention is most likely multifactorial, but are incongruent in ascribing a level of significance to individual or combinations of contributing factors. Likewise, no clear pattern emerged from comparisons of contextual (age, fluid intake, medication use) and residual (type of surgery, type of anesthesia) stimuli examined by the questions for research. Even though this lack of clarity was related to a limited number of retentive subjects and the stimuli selected for use in this study, it also affirmed the complex etiology of postoperative urinary retention.

All of the contextual stimuli selected for use in this study (age, fluid intake, medication use) were identified in the Roy Adaptation Model as common factors contributing to the development urinary retention (Roy & Andrews, 1991). Even though the Roy Model linked these stimuli to the development of urinary retention, there was no differentiation among stimuli according to time (acute versus chronic retention) or situation (e.g., postoperative, postpartum). Nonetheless, certain study findings related to the contextual and residual stimuli warrant mention.

Contextual stimuli.

Three out of the four subjects who experienced postoperative urinary retention in this study were young, 21 to 26 years old. Although this finding compares to the “surprisingly high frequency among females aged 21 - 40 discovered by Tammela et al. (1986b, p. 198), these researchers did report that the greatest incidence of postoperative urinary retention occurred in subjects over 65 years of age. Similarly, Michelson et al. (1988) reported that postoperative urinary retention occurred more frequently with advanced age, yet other researchers have failed to find the same correlation (Hozak et al. 1988; Stallard & Prescott, 1988; Walts et al., 1985).

Fluid intake in excess of 1000 ml is consistently identified as a contributing factor for the development of postoperative urinary retention (Kemp & Tabaka, 1991; Michelson et al., 1988; Petros & Bradley, 1991; Tammela et al., 1986a; Wynd et al.,

1996). All four of the retentive subjects in this study had a fluid intake in excess of 1500 ml. The relative contribution of fluid intake to the overall incidence of postoperative urinary retention in this study may have been tempered somewhat by the use of intraoperative urinary catheterization.

This study did not control for intraoperative urinary catheterization, nor were data related to this event included on the Postoperative Urinary Retention Assessment (PURA) instrument. The investigator did note a tendency for intraoperative urinary catheterization to be employed routinely at Hospital B. In addition, all cases of urinary retention occurred at Hospital B. Although these findings are noteworthy, the rationale for a difference in intraoperative patient management between the two hospital settings and the effect it had on the incidence of postoperative urinary retention is unknown.

Retentive subjects ($n = 4$) received five or more different medications with a known side effect of urinary retention during the perioperative period. In analyzing the pharmacotherapeutic classifications and time of administration for these medications, it was determined that retentive subjects received the majority as an anesthetic agent given during surgery or a narcotic analgesic administered in the postoperative period. The findings of this study were consistent with prior investigations that found no relationship between the administration of postoperative

narcotic analgesics and the incidence of postoperative urinary retention (Tammela et al., 1986b; Wynd, et al., 1996).

Residual stimuli.

The Roy Adaptation Model described residual stimuli as environmental factors that have an unknown or uncertain effect on the present situation (Roy & Andrews, 1991). The residual stimuli selected for use in this study (type of surgery and type of anesthesia) have been associated with the development of postoperative urinary retention (Petros & Bradley, 1991; Stallard & Prescott, 1988; Tammela et al., 1986a; Walts et al., 1985).

Orthopedic patients have been identified as an at-risk population for postoperative urinary retention (Hozack et al., 1988; Michelson et al., 1988; Walts et al., 1985, Wynd, et al., 1996). Three out of four retentive subjects in this study underwent an orthopedic procedure involving an extremity. The percentage of retentive subjects who underwent an orthopedic procedure in this study may be disproportionate to the percentage that could be expected with a more diverse population of general surgery patients.

In reviewing the types of surgery performed on study subjects, common surgeries, for example hysterectomy, herniorrhaphy and laparotomy, were absent in the sample. The absence of these common surgeries was related to several factors. The participation criteria eliminated women who were scheduled for surgery

involving urinary tract structures or had a physician's order to insert an indwelling urinary catheter preoperatively. Surgeons in both hospital settings routinely ordered indwelling urinary catheterization for major operations involving lower abdominal structures. In addition, fewer general surgeons assented to patient approach than surgeons who had specialized practices, such as orthopedics or ear, nose, and throat.

The literature is incongruent when describing anesthesia's contribution to the development of postoperative urinary retention. All of the retentive subjects in this study ($n = 4$) received a general anesthetic. Many of the nonretentive subjects received local or regional anesthesia and relatively few received a spinal or epidural. Therefore, the findings in this study related to type of anesthesia must be viewed with caution.

Peppermint oil.

In this study, postoperative urinary retention represented the subjects' focal stimulus in the physiological mode. The nursing intervention used to manage the focal stimulus and thereby promote adaptation, was the administration of peppermint oil. Three out of four subjects in this study voided after the administration of peppermint oil.

One could question whether or not the one subject who did not void after peppermint oil administration was truly experiencing postoperative urinary retention. This uncertainty is based upon the finding that although the subject had received over

three liters of fluid prior to a determination of postoperative urinary retention by the licensed nurse eleven hours after surgery, only 200 ml of urine was returned by straight catheterization. Given these circumstances, it is conceivable that the determination of postoperative urinary retention was made prematurely and hence, was not an appropriate situation for the administration of peppermint oil.

There were no adverse reactions to peppermint oil administration detected at either one of the two follow up assessments performed by the investigator, suggesting that peppermint oil was well tolerated by study subjects. This finding was consistent with patient response documented in prior investigations (Dew et al., 1984; Rees et al., 1979; Sparks, et al., 1995).

The Peppermint Oil Administration Protocol (POAP) served as the standard for preparation and administration of peppermint oil in this study. The POAP standard was developed from the available documented resources and anecdotal reports of peppermint oil use by practicing nurses. The POAP proved to be a useful standard in this study, however the POAP cannot be assumed to adequately represent the optimal dose, preferred administration technique, or most efficacious time for administration of peppermint oil. For example, the 0.5 cc amount of peppermint oil administered to subjects in this study was quite pungent according to nursing staff members and the investigator, and may be in excess of the amount required to produce the desired effect on urinary function.

Relatively little is known about the mechanism of action of peppermint oil in urinary tissues. Lederer et al. (1991) advocated administration by inhalation with no mention of local exposure, yet other authors (Tucker et al., 1996; Vogler, 1993) specified that peppermint oil should be administered in close proximity to the urinary meatus. In this study, peppermint oil was administered in close proximity to the subject's urinary meatus with no control for inhalation of peppermint oil vapors. Thus, it remains to be determined whether the mechanism of action for peppermint oil occurs at a local tissue level, through a more complex systemic response involving olfaction, or some interrelated combination of both.

Context of administration.

The nursing assessments/actions reported to have been used by licensed nursing staff to make a determination of postoperative urinary retention were consistent with one of the major (absence of urine output) and one of the minor (sensation of bladder fullness) defining characteristics of urinary retention specified by the North American Nursing Diagnosis Association (NANDA) (Doenges & Moorhouse, 1996). The majority of reported assessments/actions used by the licensed nurses to make a determination of postoperative urinary retention were related to subjective symptoms, and not objective assessment data. Interestingly, no licensed nurse reported having actually palpated a subject's lower abdomen to assess for bladder distention. One nurse did report that a subject had complained of suprapubic

tenderness, but it is not known how the nurse determined the existence of this tenderness.

The number of subjects dismissed prior to voiding in the postoperative period was greater than anticipated. These subjects were not followed after hospital discharge and it is not known whether they later experienced voiding difficulty, or not. As postoperative urinary retention may occur 12 or more hours after surgery (Tammela et al., 1986b) the trend to dismiss patients prior to establishing voiding ability is a noteworthy finding in this study.

Implications for Nursing

The findings of this investigation have implications for nursing research, practice, and education. The discussion of the implications for nursing research is followed by a study findings implications for nursing practice and education.

Research.

Study designs organized around select elements of the Roy Adaptation Model are considered to be a valid approach to the development of nursing knowledge (Roy & Andrews, 1991). The design of this study focused on the physiologic aspects of postoperative urinary retention and did not explore the subject's perceptions related to the three psychosocial modes of the Roy Adaptation Model. There were, however serendipitous findings that related to this unexplored aspect of the theoretical framework.

Throughout the course of this study, numerous patients and visitors were quick to share with the investigator vivid memories of “when I couldn’t go” and the various methods employed to accomplish bladder emptying. The themes that emerged from these impromptu visits with the investigator were a sense that urinary catheterization should be avoided if at all possible and the perception that peppermint oil use was a more humane, natural method to approach treatment of acute urinary retention. Surgeons, on the other hand, more often expressed a belief that the potential efficacy of peppermint oil was dubious, however the practice seemed innocuous enough to approve patient participation without concern for patient safety.

These serendipitous findings related to patient’s perspective of urinary retention underscore the importance of considering the subjective dimensions of the human experience as central to knowing and valuing, and the holistic nature of Person (Roy & Andrews, 1991). Research designs that incorporate the psychosocial and physiological dimensions of urinary retention and the perceived quality of care would provide nursing with a more meaningful understanding of the event and represent a worthwhile avenue to pursue in future research designs. In its present form, the Postoperative Urinary Retention Assessment instrument would not be useful for examination of the psychosocial modes or quality of care issues. The instrument would require substantial revision in order to be useful for data collection related to these aspects of urinary retention.

Practice and education.

The number of subjects in this study who were dismissed prior to voiding (n = 19) is a reflection of the changes that have occurred in the health care during the past two decades. The proportion of surgical patients who are classified as ambulatory or same day surgery patients has increased substantially and necessitated changes in perioperative standards of care that were originally developed for inpatients (Phipps et al., 1997). The standard of care practiced in the same day surgery units selected for use in this study required some, but not all postoperative patients to void prior to discharge. A decision to require proof of voiding ability was reportedly based primarily upon the type of surgical procedure performed and not patient characteristics. Telephone follow up interviews were routinely conducted by nursing staff the day after surgery, but questions specific to urinary functioning were reportedly not always included.

As the incidence of postoperative urinary retention is somewhat unpredictable and may represent a patient's first episode of urinary dysfunction (Anderson & Grant, 1991) the importance of educating nurses to routinely assess urinary function in all postoperative patients should not be underestimated. Urine elimination is a basic human need and assessments used to determine the adequacy of urinary functioning is a fundamental nursing responsibility (Roy & Andrews, 1991). Assessment of urinary functioning, whether conducted personally by the nurse while the patient is in the

surgical unit or as a component of a structured telephone follow up the following day, is an important element in an accurate and complete assessment of a patient's response to surgical intervention.

Beginning nursing students are instructed in nursing fundamentals textbooks to be cognizant of the potential for urinary catheterization to produce therapeutic benefit as well as significant harm. But somewhere in the transition from beginning nursing student to practicing professional, a sense of complacency often develops from the routine clinical use of urinary catheterization and successively less attention given to the risk for patient harm.

Granted, urinary catheterization is routinely employed in the medical management of acute urinary retention, but the significant risks for morbidity associated with urinary catheterization (Stallard & Prescott, 1988; Black & Matassarin-Jacobs, 1997; Tammela et al., 1986b) have not been nullified by routine use. Intervention with noninvasive nursing measures to promote voiding continues to represent an important proactive, first-line approach to prevent the incidence of acute urinary retention.

Unfortunately, many of the noninvasive nursing interventions to promote voiding lack research validation. The use of aromatic oils to promote voiding is referred to in nursing textbooks (Sherwen et al., 1995; Vogler, 1993), clinical care planning guides (Doenges & Moorhouse, 1996; Lederer et al., 1991; Sherman, 1992;

Tucker et al., 1996), and the Nursing Intervention Classification (NIC) (McCloskey & Bulechek, 1996), but little information is documented to guide the health professional on how best to administer these oils in an appropriate, safe manner. Differences are known to exist between the different types of oils and they cannot necessarily be used interchangeably. Any nursing intervention that is suggested in textbooks but not well described, or is promulgated through word-of-mouth recommendation has the potential to be deleterious when inappropriately implemented in a clinical setting.

Professional nursing standards promote the use of research based interventions that are able to produce predictable patient outcomes (ANA, 1991; Groah, 1996). Chitty (1993) argued that knowledge gained through clinical practice, albeit important, lacks the power of clinical knowledge generated by and validated through research. While Chitty's contention that research empowers practice has validity, knowledge gained through other ways of knowing should not be summarily dismissed as inappropriate or inferior. The challenge for nursing is to find an equitable balance between the various ways of knowing and to recognize the unique contribution each one makes to the whole of nursing knowledge (Chinn & Krammer, 1991).

Suggestions for Future Research

Although encouraging, the outcomes of peppermint oil use in this study do not provide substantial evidence to support the oil's efficacy for postoperative women

in particular, or individuals with acute urinary retention in general. Limitations of the present study with regard to generalizability could be addressed by investigations with other at-risk populations and larger sample sizes. For example, postpartum women and spinal cord injured patients have been identified as populations at-risk for acute urinary retention and could potentially benefit from peppermint oil administration. The difficulties in obtaining a larger sample of subjects with urinary retention in this study could be addressed by collaboration with other nurse researchers and the use of multiple settings for data collection. Interdisciplinary collaboration between nurse researchers and surgeons could promote support for establishing a patient's ability to void prior to routinely inserting an indwelling urinary catheter during the perioperative period.

Research designs that examine the efficacy of peppermint oil in male subjects would be beneficial as well. Although the male and female urinary tracts are similar, gender specific differences in structure and function do exist. Based upon these differences, the response to peppermint oil administration may differ significantly between males and females.

Limitations of the present study also could be addressed by the incorporation of more precise assessment criteria and physiological indicators for the presence of acute urinary retention. More precise identification of acute urinary retention would lessen the potential for treating unqualified subjects with peppermint oil.

Administration of peppermint oil by the licensed nursing staff member assigned to the patient's care would improve content validity and lessen the potential for extraneous variables to be introduced by the presence of an unfamiliar investigator.

The contextual and residual stimuli selected for use in this study may not represent the primary stimuli involved in the development of urinary retention. Continued investigations of urinary retention using the Roy Adaptation Model as a theoretical framework would clarify the nature and relationship of contextual and residual stimuli for acute urinary retention. Investigation of the psychosocial impact and quality of care issues would contribute to nursing knowledge and a more complete understanding of acute urinary retention and its treatment.

Conclusions

The findings of this study will be useful to future investigations of acute urinary retention and the Roy Adaptation Model. Even though this study involved a small sample size and intervention with peppermint oil was accomplished with only four subjects, the findings do represent a beginning attempt to investigate the clinical practice of using aromatic oils to stimulate voiding.

Many critical questions about oil usage remain unanswered. The site and mechanism of action for peppermint oil in urinary tissues has not been determined. In addition, the optimal dose, administration method, and timing of administration for peppermint oil have not been established. As nursing knowledge to answer these

critical questions is generated through continued research, a truly informed decision for whether or not peppermint oil merits a place in current clinical practice will become a reality.

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Appendix A

Postoperative Urinary Retention Assessment Instrument

**Postoperative Urinary Retention Assessment (PURA) Instrument
Part A**

Date: _____ Chart Number: _____ Subject number _____

Allergies _____

Date of Birth: _____ Age _____

Type of Surgical Procedure Performed: _____

Surgery Start Time _____ Surgery End Time _____

Type of Anesthesia:

General _____ Other (Specify) _____

Void: Yes / No

If yes, Time Voided _____

If no, time postoperative urinary retention determined by licensed nursing staff: _____

Fluid Intake : Record data from surgery start time until time postoperative urinary retention is determined by licensed nurse

Oral fluid intake _____ ml

Parenteral intake:

Solution	Amount		
_____	_____ ml	_____	_____ ml
_____	_____ ml	_____	_____ ml
_____	_____ ml	_____	_____ ml
_____	_____ ml	_____	_____ ml
_____	_____ ml	_____	_____ ml
Total Intake:			_____ ml

Medication Administration

Preoperative medications: Record all medications given within two hours of surgery start time.

Name	Amount	Route	Time	Retention Side Effect? (Yes/ No)
------	--------	-------	------	--

1	_____	_____	_____	_____
2	_____	_____	_____	_____
3	_____	_____	_____	_____
4	_____	_____	_____	_____
5	_____	_____	_____	_____

Name	Amount	Route	Time	Retention Side effect? (Yes/ No)
6				
7				
8				
9				
10				
11				
12				

Intraoperative Medications: Record all medications administered during surgery.

1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				

Postoperative Medications: Record all medications administered until time postoperative urinary retention is determined by licensed nurse.

1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				

_____ Total number of different medications administered

_____ Total number of medications with side effect of urinary retention

Total number of doses given for each medication with side effect of urinary retention:

Medication	# Doses
1	_____
2	_____
3	_____
4	_____
5	_____
6	_____
7	_____
8	_____
9	_____
10	_____
11	_____
12	_____

Investigator Comments: _____

Postoperative Urinary Retention Assessment (PURA) Instrument
PART B

Date: _____ Chart number: _____ Subject # _____
Timed treatment period: Start _____ Stop _____

Time peppermint oil test dose administered _____
Amount of peppermint oil administered _____

Environment during peppermint oil treatment

1. Location for voiding attempt: _____ (i.e., bed, bed side commode, bathroom)
2. Subject position _____ (i.e., supine, Fowler's)
3. Urine elimination device _____ (i.e., bed pan, commode, In-toilet device)
4. Head of bed elevation Degrees _____ (As appropriate)
5. Provide privacy?

Nursing actions to confirm retention?

Nursing measures provided by licensed nursing staff member to promote subject voiding prior to the timed treatment period?

Response to Peppermint Oil Treatment

Peppermint oil test dose: Time _____ Void: Yes _____ No _____

Initial assessment immediately after treatment: Date _____ Time _____

Perineal assessment:

Skin condition: Intact? _____ Redness? _____ Swelling? _____

Other comments _____

Subject Report:

Any feelings of pain or discomfort? _____ Any itching? _____ Any burning? _____

Other subject comments: _____

Investigator comments _____

Follow up Assessment (approximately 24 hours later) Date _____ Time _____

Perineal assessment:

Skin condition: Intact? _____ Redness? _____ Swelling? _____

Other comments _____

Subject Report:

Any feelings of pain or discomfort? _____ Any itching? _____ Any burning? _____

Other subject comments: _____

Investigator comments _____

Appendix B
Peppermint Oil Administration Protocol

Peppermint Oil Administration Protocol (POAP)

Note: In this POAP sample, selected rationales are printed in *italics*.

General Information

1. The investigator is responsible for preparation, administration, and disposal of all test doses. (*Accountability, standardization of preparation procedure*)
2. The stock bottle and prepared test doses of peppermint oil are stored under refrigeration until the time of use. (*Limits potential for deterioration of peppermint oil, warm solution has increased rate of vaporization*)
3. Test doses are prepared from one four ounce stock bottle of Peppermint Oil U.S.P. (*Standardization of test doses, pharmaceutical products labeled U.S.P. have an established standard for source, physical and chemical properties, purity and identity, and assay of the product (Kozier, Erb, Blais, & Wilkinson, 1995).*)
4. The anticipated number of test doses are prepared daily, during a single preparation period. (*Standardization of procedure*)
5. Unused test doses are disposed of intact, in sharps disposal containers. (*Limits inadvertent misuse and potential for oil deterioration from prolonged exposure to plastic syringe*)
6. Subject identity, informed consent, and known allergies are verified prior to administration of test dose. (*Subject safety*)

Equipment and Supplies

1. Four ounce stock bottle of Peppermint Oil U. S. P.
2. Bottle lid with access port (Adapta-cap, Baxa Corporation) (*Lid design limits size of bottle opening and vapor loss, access port designed to be used with the syringe selected for dose preparation*)
3. Standard plastic calibrated syringe with syringe cap (Exacta-Med, Baxa Corporation)
4. Sealable plastic bags (Ziploc Freezer Bag, DowBrands L. P.)
5. Adhesive identification labels for plastic bags

Preparation of Peppermint Oil Test Doses

1. Wash hands
2. Insure access port of bottle lid is in closed position.
3. Remove original bottle lid; carefully and quickly apply bottle lid with access port.
4. Open access port of bottle lid and insert tip of syringe.

5. Withdraw 0.5 cc test dose.
6. Remove syringe and close access port.
7. Quickly cap syringe tip using a syringe cap
8. Place prepared test dose in plastic bag and seal.
9. Affix adhesive identification label to the outside of bag.
10. Place prepared test doses in refrigerator.
11. Continue steps 4-11 until desired number of test doses for the day are prepared.
12. Follow preparation steps 1 and 4-11 on all subsequent days that test doses are prepared.

Procedure for Administration of Peppermint Oil Test Doses

1. Remove test dose from refrigeration at least one hour prior to anticipated transfer of subject to the Postanesthesia Care Unit. (*Allows oil to warm to room temperature*)
2. After an unsuccessful attempt to void during the trial period, the investigator will inform the subject that a measured amount of peppermint oil will be placed into the urine collection device.
3. Uncap the syringe and gently depress the plunger to inject the peppermint oil into the urine collection container (*Permits controlled delivery of test dose, decreased risk of inadvertent skin exposure to syringe contents*)
4. Direct oil flow to bottom of commode or in-toilet urine receptacles, or to front of bed pan, as appropriate. (*Decrease risk of skin contact when subject is repositioned on urine collection container*)
5. After voiding is accomplished or at end of 5-10 minute trial, whichever comes first, assist the subject off of the elimination device.
6. Provide perineal care with soap and water.
7. Assess perineal area and subject report of response to peppermint oil.
8. Document assessments on PURA, Part B.
9. Assist subject to reposition and provide for comfort, as indicated.
10. Repeat steps 8 and 9 the next day, approximately 24 hours after peppermint oil administration.

Appendix C
Human Subjects Committee Approval

HUMAN SUBJECTS COMMITTEE - REPORT OF ACTION

HSC#: 7210-97 TITLE: Use of Peppermint Oil to Promote Urination in Women Experiencing Postoperative Urinary RetentionRESPONSIBLE INVESTIGATOR: Cynthia S. Teel, Ph.D.DEPARTMENT: School of Nursing Administration, KUMC

EXTERNAL GRANTING AGENCY: _____ GRANT/PROTOCOL #: _____

☒ APPROVAL FOR IMPLEMENTATIONSURVEILLANCE LEVEL 2

EXEMPTION CLASS _____

☐ REVIEWED AND RECERTIFIED☐ Implementation ☐ Non-implementation☐ DISAPPROVED☐ CONDITIONAL APPROVAL
(Committee Review Required)☒ CONDITIONAL APPROVAL *
(Chairman Review Required)☐ TABLED☐ REVIEWED/NO ACTION TAKEN☐ ADMINISTRATIVE TERMINATION☐ ADMINISTRATIVE RE-INSTATEMENTNOTE: Response to Conditional
Approvals/Tabled Actions must be received
within 30 days or project will be terminated.

COMMITTEE MINUTES

This is a study to investigate the use of peppermint oil as a nursing measure for adult women experiencing postoperative urinary retention. The following clarifications and changes are required:

1. The "Nursing Staff Information Sheet" implies that the investigator will be called to the bedside of the woman experiencing postoperative urinary retention. Why is it necessary for the investigator to be physically present, especially since this step requires that a woman experiencing urinary retention wait until the investigator can be summoned to the bedside?
2. The "Nursing Staff Information Sheet" does not ask that nurses utilize a warm bath or sitz bath for the woman experiencing urinary retention prior to the utilization of the experimental intervention. Clarify why this commonly used nursing intervention will not be allowed in this study.

Consent Form:

3. Each page: Remove "Peppermint 64, Peppermint, 65," etc and substitute page numbers, i.e. "Page 1 of 3, Page 2 of 3," etc.
 4. Page 1, PROCEDURE: Delete at least some of the "I understand..." statements that start almost every sentence of this section.
 5. Page 1, PROCEDURE: Delete the reference to peppermint oil in the description of "typical actions used after surgery to help patients urinate." No clinician on our Committee has ever seen or heard of the use of peppermint oil in the context of urinary retention. This is not a "typical action." Include reference to use of warm water bath.
 6. Page 1, PROCEDURE: Avoid use of the misleading verb "administration" to describe the use of the peppermint oil. Suggest, "use." Also, see question noted in item 1 above about the need for the investigator to be summoned to the bedside of the patient.
 7. Page 1, PROCEDURE: Add a statement regarding use of urinary catheterization to relieve urinary retention if all measures, including the experimental intervention, are not successful in relieving the patient's retention.
 8. Page 2, RISKS: Suggest deletion of the first sentence.
 9. Page 2, BENEFITS: Begin this section with a statement that the subject may not benefit from participation in this activity. Avoid use of the word "administration." Delete the second sentence of this section.
 10. Page 2, COSTS: Delete the last sentence.
 11. Page 2, CONFIDENTIALITY: It is not necessary to include the specific names of the members of the thesis committee.
 12. Page 3, CONSENT: The copy of the consent form provided to the subject does not need to be signed.
- Suggestion (response/modifications not required for approval)
1. Concerns regarding Scientific Merit: Clarify why no controls are being used in this study. Control subjects could include subjects who merely smelled peppermint oil; or, subjects who had wintergreen oil placed in the urine collection device.

This project is approved with the above provisions for review by the Chairman. This action was approved unanimously. There were 11 members present and 8 absent.

CHAIRMAN'S SIGNATURE

Redacted Signature

DATE OF ACTION 06/24/97

Note: Unless indicated above, signature alone does not imply approval for implementation.

* Response to Conditions Accepted:

Redacted Signature

97

HUMAN SUBJECTS COMMITTEE - REPORT OF ACTION

HSC#: 7210-97 TITLE: Use of Peppermint Oil to Promote Urination in Women Experiencing Postoperative Urinary RetentionRESPONSIBLE INVESTIGATOR: Cynthia S. Teel, Ph.D.DEPARTMENT: School of Nursing Administration, KUMC

EXTERNAL GRANTING AGENCY: _____ GRANT/PROTOCOL #: _____

- ☒ APPROVAL FOR IMPLEMENTATION
SURVEILLANCE LEVEL 2
EXEMPTION CLASS _____
- ☐ REVIEWED AND RECERTIFIED
☐ Implementation ☐ Non-implementation
- ☐ DISAPPROVED

- ☐ CONDITIONAL APPROVAL
(Committee Review Required)
- ☐ CONDITIONAL APPROVAL *
(Chairman Review Required)
- ☐ TABLED

- ☐ REVIEWED/NO ACTION TAKEN
- ☐ ADMINISTRATIVE TERMINATION
- ☐ ADMINISTRATIVE RE-INSTATEMENT

NOTE: Response to Conditional Approvals/Tabled Actions must be received within 30 days or project will be terminated.

COMMITTEE MINUTES

This is an addendum to a previously approved project.

External Agency - N/A


Protocol Number - N/A

Study Action - Approval letter from Jon Jackson, Associate Hospital Administrator to Conduct Study.
Revised Consent Form

The addendum is approved. This action was approved unanimously.

CHAIRMAN'S SIGNATURE

Note: Unless indicated above, signature is required.


Redacted Signature

ACTION 09/23/97

plementation.

* Response to Conditions Accepted: _____

Signature (Chairman, HSC)

Date

Appendix D
Informed Consent

Study Title: Use of Peppermint Oil to Promote Urination in Women Experiencing Postoperative Urinary Retention
Primary Investigator: Cynthia Teel, Ph.D.
Co-investigator: Shirley Phillips, R.N., M.S.

INFORMED CONSENT

INTRODUCTION

I understand that as a female patient scheduled for a surgical operation, I am being invited to participate in a study to investigate factors influencing a woman's ability to urinate after surgery. This study will be conducted at the University of Kansas Medical Center while I am a patient in the surgical unit. Shirley Phillips R.N., M.S., a Master's student at the University of Kansas School of Nursing, will be conducting this study under the direction of Dr. Cynthia Teel (913-588-1697).

PURPOSE

The purpose of this study is to investigate measures used by nurses to help women urinate (pass water) in the time period immediately following surgery.

PROCEDURE

My participation will involve having nurses perform nursing care actions to help me urinate after surgery. I understand that these nursing actions, such as running water in a sink and sitting in a bath of warm water are typical actions used after surgery to help patients urinate. If I am unable to urinate after these typical nursing actions are performed by the hospital nursing staff, Shirley Phillips will be notified. Shirley Phillips will come to my bed side and peppermint oil will be used as a nursing action to help me urinate. Shirley Phillips will also need to look at my perineum (my private parts close to where I pass urine) after the administration of peppermint oil and again the following day. If I am dismissed from the hospital before Shirley Phillips visits me on the following day, she will telephone me to check on the condition of my perineum.

If I am not able to urinate after the typical nursing actions and the peppermint oil are used, a urinary catheter (urine tube) may be ordered by my physician to drain the urine from my bladder.

I understand that my doctor is aware that this study is being conducted and knows that I am being ask to participate. I understand that my participation will not change or prolong the usual course of care provided to patients after surgery to help them urinate. Participation or nonparticipation with this study will not jeopardize my care in any way now or in the future and any treatment deemed necessary by my doctor will be provided.

Page 1 of 3

RISKS

If peppermint oil is used, care will be taken to avoid direct contact with my skin. Risks associated with the use of peppermint oil includes possible skin irritation and any unpleasantness associated with the odor of peppermint oil.

BENEFITS

I understand that I may not benefit from participation in this study. Potential benefits for participation in this study include successful urination after the use of peppermint oil.

COSTS

I understand that my participation in this study is voluntary and I will not receive any compensation for participation. There is no financial cost for my participation in this study.

INSTITUTIONAL DISCLAIMER STATEMENT

I understand that, although the University of Kansas Medical Center does not provide free medical treatment or other forms of compensation to persons injured as a result of participating in research, such compensation may be provided under the terms of the Kansas Tort Claims Act. If I believe I have been injured as a result of participating in research, I should contact the Office of Legal Counsel, University of Kansas Medical Center, Kansas City, Kansas 66103.

CONFIDENTIALITY

I understand that the investigators will not use my name on any research records. I understand the Shirley Phillips will keep confidential research records and information from this study. However, I realize that Shirley Phillips may need to let others look at the records of my participation. I agree to let the members of the investigator's thesis committee see my records. I understand that the investigator will not reveal my identity if the results of this study are published.

QUESTIONS

I have read the information in this form. I have had the opportunity to ask questions, and my questions have been answered to my satisfaction by the co-investigator, Shirley Phillips. I know that if I have any more questions after signing this form, I may contact Shirley Phillips at 316-343-6800, extension 648 or Dr. Cynthia Teel at 913-588-1697.

CONSENT

Shirley Phillips has given me information about what will be done to me in this research study. Shirley Phillips told me how it will be done, what I will have to do, and how long the research will take. I have been told about any inconvenience, discomfort or risks I may experience due to this research. Shirley Phillips has explained how this research may affect me or my health. I agree to take part in this research study as a research subject. I am aware that I may quit or refuse any part of the research study at anytime. I understand that quitting or refusing any part of the study will have no effect upon the medical or nursing care or treatment I receive now or in the future.

I understand that the investigators will give me a copy of this form to keep for my records.

Date

Print Subject's Name

Subject's Signature

Date

Co- Investigator's Signature

Phone : 316-343-6800 Extension 648

Appendix E
Agency Approval

The University of Kansas Medical Center

The University of Kansas Hospital
Hospital Executive Office

Shirley A. Phillips, RN
1927 Road 110
Hartford, KS 66854

Dear Ms. Phillips:

You have informed me that the purpose of this research study ("Use of Peppermint Oil to Promote Urination in Women Experiencing Postoperative Urinary Retention") is to investigate the use of peppermint oil as a nursing measure to promote voiding for patients experiencing postoperative urinary retention. The information gathered in this study is for use in completing your Master's thesis under the direction of Cynthia Teel, R.N., Ph.D.

For the purpose of this study, patients who develop postoperative urinary retention at the University of Kansas Hospital and who consent to participate in the study, will have a test dose of peppermint oil administered by you to promote urination. The patients' attending surgeon must approve the use of peppermint oil prior to administration. You have informed me that the risks and benefits of patient participation in this study are comparable to those that could reasonably be expected whenever nursing actions to promote urination are performed and that care will be taken to avoid direct skin contact with the peppermint oil. You understand that the University of Kansas Medical Center College of Health Sciences and Hospital does not maintain a policy of medical treatment or compensation for physical injuries incurred as a result of participating in biomedical or behavioral research. Data collection for study patients at the University of Kansas Hospital is scheduled to occur in July, August and September, 1997.

Patients' names, responses and other known history of the participants will not be identified when reporting this study. Patients will be informed that their health care will not be jeopardized by participation or nonparticipation in the study. Patients may withdraw at any time from the study without prejudice.

This study has been explained to me and has been reviewed by Ann Babb, Interim Chief Nurse Executive, at the University of Kansas Hospital. The Hospital is willing for patients to participate as long as the individual patient and attending surgeon give their consent and the research study has the approval of the Human Subjects Committee at the University of Kansas Medical Center.

Sincerely,

Redacted Signature

Jon Jackson
Associate Hospital Administrator

I have been informed by Shirley Phillips R.N., a Master's nursing student at the University of Kansas, that the purpose of this research study is to investigate the use of peppermint oil as a nursing measure to promote voiding for patients experiencing postoperative urinary retention. The information gathered in this study is for use by Shirley Phillips in completing her Master's thesis under the direction of Cynthia Teel, R.N. Ph.D.

I understand that patients who develop postoperative urinary retention at Newman Memorial County Hospital will have a test dose of peppermint oil administered by Shirley Phillips to promote urination. I am aware that the patients' attending surgeon will approve the use of peppermint oil prior to administration after surgery. I understand that the risks and benefits of patient participation in this study are comparable to those that could reasonably be expected whenever nursing actions to promote urination are performed and that care will be taken to avoid direct skin contact with the peppermint oil. I understand that the University of Kansas Medical Center College of Health Sciences and Hospital does not maintain a policy of medical treatment or compensation for physical injuries incurred as a result of participating in biomedical or behavioral research.

I am aware that the patients' names, responses, and other known history of the participants will not be identified when reporting this study. Patients will be informed that their health care will not be jeopardized by participation or nonparticipation in the study. I understand that patients may withdraw at any time from the study without prejudice.

This study has been explained to me, and I am willing for patients to participate as long as the individual patient gives their consent and the research study has the approval of the Human Subjects Committee at the University of Kansas Medical Center.

Participation in this study was approved by the Graduate School, Dept of NMCH on 6-5-97 by the Graduate School in this document.

Redacted Signature



PAULA J. WILSON, R.N., M.A., C.N.A.
Assistant Administrator / Chief Nursing Officer

12th and Chestnut
Emporia, Kansas 66801

(316) 343-6800, Ext. 602
pjwilson@cadvantage.com

I have been informed by Shirley Phillips R.N., a Master's nursing student at the University of Kansas, that the purpose of this research study is to investigate the use of peppermint oil as a nursing measure to promote voiding for patients experiencing postoperative urinary retention. The information gathered in this study is for use by Shirley Phillips in completing her Master's thesis under the direction of Cynthia Teel, R.N. Ph.D.

I understand that patients who develop postoperative urinary retention at Newman Memorial County Hospital will have a test dose of peppermint oil administered by Shirley Phillips to promote urination. I am aware that the patients' attending surgeon will approve the use of peppermint oil prior to administration after surgery. I understand that the risks and benefits of patient participation in this study are comparable to those that could reasonably be expected whenever nursing actions to promote urination are performed and that care will be taken to avoid direct skin contact with the peppermint oil. I understand that the University of Kansas Medical Center College of Health Sciences and Hospital does not maintain a policy of medical treatment or compensation for physical injuries incurred as a result of participating in biomedical or behavioral research.

I am aware that the patients' names, responses, and other known history of the participants will not be identified when reporting this study. Patients will be informed that their health care will not be jeopardized by participation or nonparticipation in the study. I understand that patients may withdraw at any time from the study without prejudice.

This study has been explained to me, and I am willing for patients to participate as long as the individual patient gives their consent and the research study has the approval of the Human Subjects Committee at the University of Kansas Medical Center.

Redacted Signature

6-9-97

Signature

Susie Titus
Clinical Director
Medical, Surgical &
Pediatric Units

Appendix F
Sample Letter to Medical Physicians

August 19, 1997

Dr. James Barnett
1301 West 12 th
Emporia, Kansas 66801

Dear Dr. Barnett,

I am a graduate nursing student in the University of Kansas School of Nursing Master's degree program. During the next few months, I will be conducting the "Use of Peppermint Oil to Promote Urination in Women Experiencing Postoperative Urinary Retention" study at Newman Memorial County Hospital and the University of Kansas Medical Center. In this study, participants who experience postoperative urinary retention during the first 12 hours after surgery will have a test dose of peppermint oil used externally in a bed pan, commode, or specimen to promote voiding.

The study has been approved for implementation at NMCH by the Human Subjects Committee at the University of Kansas Medical Center, the Leadership Group of NMCH, Paula Wilson, Assistant Administrator/Chief Nursing Officer, and Susie Titus, MSP Clinical Director. Permission to approach female surgical patients has been granted by Dr. Kosko, Dr. Harris, Dr. Bosiljevac Dr. Edwards, Dr. Glenn, and Dr. Montgomery.

As you may be involved with the medical care and treatment of female patients who are potential subjects for this study and/or may be unfamiliar with the use of peppermint oil in this population, I have enclosed a study proposal for your review. The proposal describes the study and process planned for data collection. Data collection will begin in August at NMCH.

If you have any questions or concerns about the proposed study or the use of peppermint oil for postoperative female patients under your care, I would be happy to visit with you either in person or by phone. I may be contacted at either one of the phone numbers listed below.
Thank you.

Sincerely,

Shirley Phillips R.N.
Work: 316-343-6800 ext. 648
Home: 316-392-5662

Appendix G
Surgeon Approval

Physician Consent Form

I give my permission for Shirley Phillips, R.N., to contact female patients under my care on surgical units 41, 43, 45, 51, 55 and Same Day Surgery at the University of Kansas Medical Center, explain the study "Use of Peppermint Oil to Promote Urination in Women Experiencing Postoperative Urinary Retention", and ask the patients to participate in the study. I have been informed by Shirley Phillips, a Master's nursing student at the University of Kansas, that the purpose of this research study is to investigate the use of peppermint oil as a nursing measure to promote voiding for female patients experiencing postoperative urinary retention. The information gathered in this study is for use by Shirley Phillips in completing her Master's thesis under the direction of Cynthia Teel, R.N. Ph.D.

I understand that this study will in no way minimize the quality or quantity of medical care the patient will receive, nor will it interfere with overall patient care. I understand that patients under my care who consent to participate will have the usual and customary perioperative nursing care provided by the nursing staff of the University of Kansas Medical Center. In the event that the patient develops postoperative urinary retention, I understand Shirley Phillips will administer a test dose of peppermint oil to promote urination. I am aware that care will be taken to avoid direct skin contact with the peppermint oil. I am aware that Shirley Phillips will assess the patient's response to the peppermint oil immediately after use and again approximately 24 hours later.

I understand that patients who are asked to participate will be assured that confidentiality will be maintained and no names of the subjects will be identified in reporting the results of this study. I understand that the patients may withdraw from the study at anytime by requesting to do so.

I am willing for patients under my care to participate as long as the individual patients give their consent. The research study has the approval of the Human Subjects Committee at the University of Kansas Medical Center. I understand that the University of Kansas Medical Center College of Health Sciences and Hospital does not maintain a policy of medical treatment or compensation for physical injuries incurred as a result of participating in biomedical or behavioral research.

Please indicate your response by placing an "X" in the appropriate box below.

- ☐ I do give my permission for Shirley Phillips to approach female surgical patients under my care.
- ☐ I do not give my permission for Shirley Phillips to approach female surgical patients under my care.

Date

Physician Signature
Dr. Edward Bruce Toby

Appendix H
Nursing Staff Information Sheet

Nursing Staff Information Sheet

_____ has consented to participate in a research study involving nursing measures to promote voiding in postoperative patients. This study is being conducted on your clinical unit by Shirley Phillips R.N. M.S.

In order to obtain accurate and complete data for this study, I need your assistance. I am asking that you do the following:

1. Perform the usual and customary postoperative care per unit and hospital routine. Routine postoperative care includes providing the usual nursing interventions to assist a patient to void and assessing urinary status.
2. If the patient is unable to urinate after the usual nursing interventions and has developed postoperative urinary retention during the time frame specified on the sticker affixed to the front of the patient chart, notify Shirley Phillips (978-6183) immediately
3. Once you have notified Shirley Phillips that the patient has developed postoperative urinary retention, do not continue to have the patient attempt to void. Shirley Phillips will notify you immediately if she will or will not be able to come to the patient's room within 5 minutes of your phone call.
4. If Shirley Phillips notifies you that she will be unable to come to the patient's bedside within 5 minutes, the patient will no longer be considered a study subject.
5. When Shirley Phillips arrives at the patient's bedside, she will place a test dose of peppermint oil in the patient's urine collection device. The patient will be positioned on the urine collection device, privacy provided, and the patient will be given an opportunity to attempt to void. The time period for the patient attempt to void will be limited to 5-10 minutes.
6. If the patient voids during this 5-10 minute period, the urine collection device will be removed and perineal care with soap and water will be provided. All voided urine will be measured and disposed of in keeping with established hospital protocol.
7. If the patient is unable to void, the urine collection device will be removed and perineal care with soap and water will be provided. The nursing staff is responsible for all follow up nursing care to provide for patient comfort, safety, and urine elimination.
8. Shirley Phillips will assess the patient's response to the peppermint oil administration immediately and again in 24 hours.
9. After the completion of the peppermint oil intervention, the nursing staff will be responsible for providing the usual and customary postoperative care for the patient.
10. If you have any questions, you may contact Shirley Phillips at 316-343-6800 ext. 648.

Appendix I
Chart Sticker

Peppermint Oil Study

Date _____

Start Time: _____

End Time